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Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

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Improving Quality of Care Assessment and Assurance

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Program Evaluation and
Methodology Division

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The Honorable Fortney H. Stark
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

This report summarizes GAO's findings on systems for measuring and monitoring the quality of care provided to Medicare beneficiaries. As you requested, and as subsequently agreed with your office, we have reviewed the Health Care Financing Administration's medical review systems, examined available data and quality assessment methods, and determined what could be done in the relatively short term to provide better information on Medicare quality of care. We also reviewed quality assurance research and evaluation activities within the Department of Health and Human Services and assessed the need for longer term changes.

We make recommendations to the Department of Health and Human Services regarding the need for systematic evaluation of quality review methods, better coordination among the quality-related activities of Medicare contractors, and improvements to data systems designed to provide better information on the incidence and distribution of quality of care problems. In addition, the report includes a matter for consideration by the Subcommittee concerning the need to assign specific responsibility for quality assurance research and development.

We obtained official comments on the draft report from the Department of Health and Human Services. The Department's comments and our response are presented in appendix VII.

Copies of the report will be made available to the Department of Health and Human Services and any others who request them.

Sincerely yours,

Eleanor Chelimsky
Director

Executive Summary

Purpose

Over 31 million elderly and disabled Americans depend on Medicare coverage for their health care. Very complex oversight systems have evolved within the Medicare program to review the services for which payments are made. Whether these systems can ensure the quality of care provided to program beneficiaries is the focus of this study. Requested by the Subcommittee on Health of the House Committee on Ways and Means on March 3, 1986, the study has two broad objectives. The first is to assess current systems for measuring and monitoring Medicare quality of care. This includes reviewing what the systems are intended to do, examining available data and quality assessment methods, and determining whether more could be done with existing data, in the relatively short term, to provide better information. The second is to review quality assessment research and evaluation within the Department of Health and Human Services (HHS), analyze its relationship to ongoing quality assessment functions, and assess the need for longer term changes.

Background

The federal government spent over $70 billion in 1987 for health care benefits for Medicare enrollees. Major program responsibilities for medical review and quality assessment are divided among three sets of organizations: (1) intermediaries and carriers, responsible for processing and paying Medicare hospital insurance and supplementary medical insurance claims; (2) Utilization and Quality Control Peer Review Organizations (PROs), currently responsible primarily for review of inpatient hospital care; and (3) HHS's Health Care Financing Administration (HCFA), which oversees these contractors and manages program data.

Until 1983, Medicare reimbursed most health care practitioners and suppliers on a fee-for-service basis, and most institutionally-based providers on a cost basis. These payment methods generally provide incentives to overuse services because the more services furnished, the more reimbursement received from Medicare. To help contain costs, however, HCFA introduced a hospital payment system for Medicare based on prospectively determined fixed payments and intensified efforts to promote participation in prepaid health care plans. Under these arrangements, the financial incentives could lead providers in some health care settings to underserve beneficiaries. Thus, Medicare has created a mixed set of reimbursement incentives for providers and practitioners that could lead to inappropriate uses of health services, as well as to inappropriate denials of services. Controlling against potential adverse consequences of these incentives requires new approaches for quality assurance.

Results in Brief

GAO found reasons for concern about current systems for monitoring Medicare quality of care. Review methods of uncertain validity are being used, quality of care problems identified by one set of reviewers are not coordinated for action by others, and the accuracy of key information is questionable. Further, HHS's strategy for developing quality assurance methods is inadequate to meet future program needs. GAO identified short-term efforts that could lead to significant improvements in the problems identified. However, GAO also found that developing a comprehensive quality assurance research base and creating a program for incorporating this knowledge into Medicare quality assurance efforts would require a long-term commitment that cannot be adequately supported by current resources.

Principal Findings

The Effectiveness of Review Methods Has Not Been Evaluated

The effectiveness of the medical review activities of carriers, intermediaries, and PROS in identifying quality problems or positively changing physician or provider behavior has not been evaluated. The oversight of medical review activities focuses on whether they meet contract specifications, most of which relate to controlling utilization, rather than on whether these activities effectively identify quality problems or lead to improvements in medical care.

Quality-Related Review Activities Are Poorly Coordinated

The medical review activities of carriers, intermediaries, and PROS with respect to quality of care are virtually independent. Each set of reviewers applies both its own and HCFA-developed computer and manual edits and screens to billing and medical record data. They independently build profiles of provider or practitioner performance to identify possibly problematic patterns of service delivery or patient outcomes. Profiling results are not routinely shared among PROS, carriers, or intermediaries reviewing care in the same geographic areas. Possible quality of care problems found by carriers and intermediaries are not systematically reported to either HCFA or PROS. If a patient qualifies for Medicare posthospital services and the intermediary suspects that the hospital discharge may have been premature, HCFA is notified. But if posthospital coverage is denied by Medicare, there is no mechanism, other than beneficiary complaints, for notifying either HCFA or PROS about possibly inappropriate or premature discharges. HCFA's planned reorganization of Medicare data systems provides an opportunity to substantially improve coordination of quality monitoring activities.

Quality of Care Data Are of Questionable Accuracy and Not Generalizable

The data that support medical review as well as the information generated by the reviews are of questionable accuracy. GAO's review indicates, however, that information on patient diagnosis on outpatient physician bills can prove useful in identifying possible utilization and quality problems; some carriers have independently added this information to their screening systems. Neither the independent activities of each contract review system, nor the HCFA systems for validating the accuracy of medical reviews are currently designed to generate national estimates of the incidence or distribution of quality problems. However, HHS plans for improvements in surveying long-term care facilities offer possibilities for generating useful national, longitudinal data on patients' rehabilitative and chronic care needs and associated quality problems.

HHS's Strategy for Research and Development on Quality Assurance Is Inadequate

HHS is supporting many useful studies addressing aspects of quality of care and, in particular, studies related to refining measures of health care outcomes. Nevertheless, GAO found no clearly defined strategy or organizational structure for integrating information on the quality of health care provided to Medicare beneficiaries or for developing the underlying methods and knowledge base to meet future needs. This strategy needs to include the development of a structured program to specify good clinical practice, incorporate that practice into standards and quality assurance methods, and test incentives for practitioners to adopt them. Without this, Medicare will continue to be unable to provide the information needed to ensure Medicare quality of care. Developing a comprehensive Medicare quality assurance program would require additional funding of research, evaluation, and quality assessment program operations.

Recommendations to the Secretary of HHS

To strengthen the process of medical review, GAO recommends evaluations of (1) the comparative effectiveness of carrier and intermediary screens and profiles as means to identify inappropriate and substandard care (p. 39), (2) the methods PROS use to review medical records and the utility of current methods for establishing their quality of care contract objectives (p. 64), and (3) the methods PROS use to review quality of care in Medicare prepaid health plans (p. 64). To improve coordination of medical review activities, GAO recommends (4) that formal guidelines be developed to coordinate the systematic and timely reporting by carriers and intermediaries to PROS and HCFA of possible quality of care problems (p. 41), and (5) that studies be initiated to assess the strengths and weaknesses of the division of responsibilities among carriers, intermediaries, and PROS for processing and screening Medicare claims data and performing medical reviews to identify quality of care problems and substandard providers and suppliers (p. 64). To improve Medicare quality of care data, GAO recommends that (6) PROs, intermediaries, and carriers document and report incidents in which key data elements for monitoring quality of care are inaccurate (p. 82), (7) physicians provide diagnostic information on part B claims submitted to carriers, who would forward this information to HCFA for inclusion in central data files (p. 81), and (8) the data used to evaluate PRO medical reviews include the information necessary to generate national estimates of quality problems (p. 83). Finally (9), GAO recommends a high priority be assigned to developing a centralized data file including nationally representative information on the health care status, care needs, and health care outcomes of home health care patients as well as nursing home residents (p. 83).

Matter for Consideration by the Subcommittee

The Subcommittee on Health should consider developing legislative proposals to assign specific research and development responsibilities to a new federal entity or existing entities for (1) developing, disseminating, and coordinating activities intended to define good medical practice and develop improved quality assurance methods, and (2) incorporating this knowledge into Medicare quality assurance efforts. Possible locations for these activities are discussed in chapter 7 (p. 110).

Agency Comments

HHS agrees in principle with all or part of most of GAO's recommendations, but has not presented specific plans for implementing changes. The agency does not agree with GAO's recommendation for addressing errors in billing, and has concerns about the possible cost of evaluating the utility of screening by claims processors to detect potential quality of care problems. HHS also disagrees with aspects of GAO's recommendation regarding the evaluation of PRO reviews of care provided in prepaid health care plans. Finally, HHS does not support the creation of a new federal entity responsible for the development of quality assurance methods, but does state that improvements in internal coordination efforts will be considered. HHS believes that a new federal entity would create problems of duplication of effort. GAO's view is that such an entity, which could be located in new or existing HHS offices, would perform key functions essential for sound quality assurance that are not currently the clear responsibility of any HHS office or agency. The full text of HHS comments and our response are presented in appendix VII.

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Abbreviations

ASPE	Office of the Assistant Secretary for Planning and Evaluation
B-MAD	Part B Medicare annual data file
CMP	Competitive medical plan
COSTAR	Computer-stored ambulatory record
CPEP	Contractor Performance and Evaluation Program
CPHA	Commission on Professional and Hospital Activities
DRG	Diagnosis-related group
EMCRO	Experimental Medical Care Review Organization
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HMO	Health maintenance organization
HSQB	Health Standards Quality Bureau
ICD-9-CM	International Classification of Diseases--9th Revision--Clinical Modification
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MADRS	Medicare automated data retrieval system
MEDPAR	Medicare provider and review file
NCHSR HCTA	National Center for Health Services Research and Health Care Technology Assessment
NIH	National Institutes of Health
OBRA 1986	Omnibus Budget Reconciliation Act of 1986
ORD	Office of Research and Demonstrations
PPS	Prospective payment system
PRISM	Project to Redesign Information Systems Management
PRO	Utilization and Quality Control Peer Review Organization
PROMPTS-2	PRO Monitoring Protocol and Tracking System
PSRO	Professional Standards Review Organization
QRO	Quality Review Organization
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982

Introduction

The federal government currently spends over $70 billion annually on behalf of about 31 million Americans enrolled in the Medicare program. Since the program was established in 1965, the Congress and Medicare officials have faced difficult decisions about whether the quality of care beneficiaries receive properly reflects the level of Medicare reimbursement, or whether, conversely, the level of Medicare reimbursement can support medical services of adequate quality.

Prior to 1983, Medicare reimbursed most physicians, other practitioners, and suppliers on a fee-for-service basis, and most institutionally-based providers on a cost basis. Medical review activities have therefore focused primarily on determining the necessity of services provided, since fee-for-service and cost-based reimbursement incentives were thought to promote overutilization of services, rather than underutilization. More recent efforts to contain program expenditures have altered the incentives for many participating health care providers. Medicare now pays for most hospital care using a system based on prospectively determined fixed payments. In addition, the program is encouraging participation in prepaid health care plans, health maintenance organizations (HMOS) and competitive medical plans (CMPS), in which a fixed fee is paid to a health care organization offering the full range of Medicare-covered services to enrollees. Under these arrangements the financial incentives could lead to underserving beneficiaries. Thus, Medicare has created a mixed set of incentives that could lead to underserving beneficiaries in some health care settings such as hospitals, while maintaining payment arrangements which could lead to overuse of services in others, such as physicians' offices.

This mixed set of reimbursement incentives complicates the task of quality assurance. Medicare needs to organize quality of care reviews to guard against potentially negative effects of all program incentives. At the same time, the review system should be comprehensive and flexible enough to adapt to new sets of circumstances brought about by future changes in program policies.

Objectives, Scope, and Methodology

Objectives

Two broad study objectives were posed in a request received from the Subcommittee on Health of the House Committee on Ways and Means on

March 3, 1986. (See appendix I.) First, we were asked to describe what current Medicare systems for measuring and monitoring quality of care are intended to do, what data and methods for assessing quality are available, and whether more could be done with existing data, in the relatively short term, to provide better information on quality of care. Second, we were asked to review the focus and direction of HHS quality review research and evaluation activities, their relationship to ongoing quality assessment functions, and whether longer term changes are needed.

Scope

We examined all quality-related activities performed by the Health Care Financing Administration (HCFA) for all Medicare-covered services. This includes all activities performed by HCFA or its contractors to ensure that care provided to program beneficiaries meets professionally recognized standards, as reflected by the structure of care (physical plant and equipment, staffing, professional training, organization, use of technology), the process of care (the provision of care itself, including the diagnostic information gathered, procedures used, therapies), and health care outcomes (recovery rates, complications, mortality or morbidity rates).

In distinguishing among structural, process-oriented, and outcome-based approaches to assessing quality of care, we followed the quality of care constructs typically found in the published literature.[1] However, there is no straightforward formula that the Medicare program, health care providers, or program beneficiaries can use in deciding how different approaches to measuring quality should be combined in an overall assessment of quality. Each approach provides different types of information: structural measures indicate whether the resources necessary to provide quality care are available; process measures, whether the care provided reflects sound medical practice; outcome measures, whether the results of care are good, bad, or indifferent. Each, moreover, allows different levels of direct involvement and control by practitioners, patients, and third-party payors or regulators. One challenge for the Medicare program is determining the optimal allocation of resources to these various approaches to quality assessment.

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[1] See, for example, A. Donabedian, Explorations in Quality Assessment and Monitoring, vol. 1, The Definition of Quality and Approaches to Its Assessment (Ann Arbor, Mich: Health Administration Press, 1980); K. N. Lohr and R. H. Brook, Quality Assurance in Medicine: Experience in the Public Sector (Santa Monica, Calif.: The Rand Corporation, October 1984); G. T. Hammons, R. H. Brook, and J. P. Newhouse, Selected Alternatives for Paying Physicians Under the Medicare Program (Santa Monica, Calif.: The Rand Corporation, 1986).

Further, we addressed both quality assessment and quality assurance activities. Quality assessment involves the application of measures of quality using either implicit or explicit criteria to the structure, process, or outcomes of care and the monitoring of levels of quality over time. Quality assurance extends the concept of assessment to include the formal organization of activities designed to identify problems in the quality of medical care, determine solutions to them, monitor the effectiveness of the solutions, and institute additional change and monitoring where warranted.[illegible] The critical distinction between quality assessment and quality assurance is that the latter includes information feedback and improvement, intended to assure enhanced levels of quality in the future.

Methodology

Medicare quality assessment and assurance activities. We conducted interviews, literature reviews, and surveys of Medicare contractors to determine what is currently being done by the Department of Health and Human Services (HHS), and in particular by HCFA, to monitor the quality of care in Medicare services. Data collection was completed in fall 1987.

We interviewed HCFA program officials and staff and obtained supporting materials (copies of project plans, data system documentation, and so forth). We examined information systems closely, reviewing the existing literature and documentation related to the structure, organization, and technical adequacy (accuracy, validity, comparability, and interpretability) of HCFA data files and information reporting systems as they pertain to quality assessment and quality assurance. In addition, we met with professional staff of several Utilization and Quality Control Peer Review Organizations (PROs), the organizations responsible for reviewing the quality of inpatient hospital care, and Medicare intermediaries and carriers (Medicare's claims processing contractors).

We formally requested descriptions and points of contact for additional information on HHS research, evaluation, and related activities focusing

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[illegible] These definitions follow closely those developed by R. H. Brook and K. N. Lohr in "Efficacy, Effectiveness, Variations, and Quality: Boundary-crossing Research," Medical Care (May 1985) p. 711; A. Donabedian, Explorations in Quality Assessment and Monitoring, vol. 3, The Methods and Findings of Quality Assessment and Monitoring: An Illustrated Analysis (Ann Arbor, Mich.: Health Administration Press, 1985) pp. 451-4; and F. Baker, "Quality Assurance and Program Evaluation," Evaluation and the Health Professions (June 1983), pp. 152-3.

on the quality of care in Medicare services. We then obtained information from key research and evaluation specialists, and HHS provided additional information as requested.

We also conducted a survey of all Medicare claims processors regarding their reviews of medical care utilization and the information related to quality of care they generate and use in the course of their work. A description of the survey methodology and findings is included in appendix III.

The adequacy of ongoing quality assessment activities and proposals for improvements. The methodology for assessing the adequacy of HCFA's ongoing quality monitoring and measurement activities consisted of a two-stage process of information gathering and synthesis.

First, we prepared detailed papers summarizing (1) the legislative, administrative, organizational, and methodological issues underlying quality of care review in the Medicare program, (2) the range of state-of-the-art methodologies currently available for quality of care assessment and their applicability to quality assessment in the Medicare program, and (3) the activities of HCFA and its contractors (that is, intermediaries, carriers, and Peer Review Organizations) with regard to quality assessment and the data currently generated. The data sources for these three papers were the literature reviews and interviews with HCFA staff and contractors described above, supplemented by a series of interviews and written communications with health services researchers across the United States and in Canada, Europe, and Australia, and private-sector health care cost-containment experts.

The second phase of our analysis involved the use of a panel of nationally recognized experts on health care delivery, quality assessment, and evaluation. The individuals serving on this panel are listed in appendix II. In addition to providing advice and information relating to their particular areas of expertise, we asked the consultants to review the background papers and to help identify from these materials (1) basic Medicare quality assessment issues that need to be addressed, and (2) the implications of the issues for improvements that would be both useful and feasible within the current constraints of the Medicare program. Subcommittee staff requested that the materials presented in the background papers be included, to the extent possible, in this report.

In January 1987, the panel members participated in a structured 1-1/2 day meeting with project staff. In the initial sessions, panel members discussed a range of issues and concerns related to the purpose and scope of quality assessment in the Medicare program. The final sessions were used to identify possible short-term improvements in Medicare systems for collecting and using information related to the quality of care, as well as longer term proposals for developing new types of information on quality.

Study Overview

This report provides the underlying documentation for, and expands upon our preliminary analyses of, strategies for measuring and monitoring Medicare quality of care, which were reported in July 1987.[1] That report presented the initial findings of our staff background papers in summary form, supplemental information provided by the consultant panel, and limited additional analyses conducted subsequent to the January 1987 panel meeting. The material presented here reflects further analyses of the feasibility and potential costs of specific options for changes addressed in the briefing report, our findings on the current status of Medicare quality assessment activities, and the rationale leading to recommendations for change.

Preliminary Analysis

In our briefing report, we indicated that problems in developing effective methods to measure and monitor quality of care involve not only technical problems related to the availability of methods and information, but also policy issues, including the basic intent and operation of quality assessment in the Medicare program. We discussed a set of general issues related to the scope of quality assessment activities, the organization of efforts to advance the state of knowledge about quality assessment, the involvement of the medical community in Medicare review activities, and the consistency of HCFA's policy objectives as they affect quality assurance.

Four possible short-term strategies for improvement were outlined in the preliminary report: (1) adding uniformly coded diagnostic data to Medicare physician (part B) claims as part of the ongoing redesign of the Medicare data system; (2) producing information on the validity and effectiveness of current methods used to screen for possible quality of care problems and to profile provider performance; (3) evaluating new programs that review the quality of care in Medicare capitated health care plans in order to provide comparative information on methods for assessing quality, as well as on levels of quality across alternative delivery systems; and (4) using Medicare and Medicaid survey and certification inspection data to generate nationally representative information on the quality of care and the care needs of Medicare patients in subacute care settings.

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[1] U.S. General Accounting Office, Medicare: Preliminary Strategies for Assessing Quality of Care, GAO/PEMD-87-15BR (Washington, D.C.: July 1987).

We also discussed three possible strategies for producing comprehensive quality of care information that would require a relatively longer timeframe for planning and implementation: (1) better integration of the data collection and monitoring responsibilities of Medicare claims processors and PROS; (2) creating a program to evaluate options for incorporating valid and reliable medical record review methodologies into peer reviews; and (3) creating epidemiological data bases, drawn from the entire Medicare population or from specific subpopulations in order to provide indepth longitudinal data on the full range of Medicare beneficiaries' health care needs, use of services, and care outcomes.

Report Organization

In this report we describe current HCFA quality assurance activities and the information they generate in order to illustrate the strengths and limitations of current approaches and the context in which our recommendations are offered.

Chapter 2 summarizes current requirements for assessing the utilization and quality of Medicare services and the highly decentralized fashion in which they are implemented. Chapters 3 and 4 discuss the major responsibilities of the carriers, intermediaries, and PROS for reviewing medical services at the individual patient level. Chapter 5 reviews the data generated by carriers, intermediaries, and PROS, and the usefulness of these and other data maintained by HCFA for assessing quality of care. Chapters 4 and 5 contain short-term recommendations for improvements in the operation and oversight of Medicare medical reviews and HCFA data systems.

Chapters 6 and 7 focus on longer term research and development issues. In chapter 6, we discuss some underlying methods and measurement questions that are crucial to generating valid and reliable information on the quality of care provided to Medicare beneficiaries and reducing quality problems. Chapter 7 contains a matter for consideration by the Subcommittee pertaining to an expanded federal effort to develop and implement improved quality assurance techniques and alternative organizational configurations for achieving that end.

Legislative and Regulatory Requirements

Medicare legislation and regulations require a range of activities intended to help ensure that Medicare beneficiaries receive quality care. Quality assessment activities have not, however, been designed as integral parts of a comprehensive quality assurance system, but rather, have evolved as ways of addressing particular program concerns. Most are designed to prevent substandard health care providers from participating in the program and to withhold payment for unnecessary, inappropriate, or poor quality care. In addition, HCFA has been charged with determining whether changes in Medicare policy, and in particular, reimbursement methods, have affected the quality of care available to beneficiaries.

Ensuring That Facilities and Providers Meet Standards

Medicare was expected to raise the general standards for acute care in the United States by requiring that participating providers conform to national professional standards. Separate "conditions of participation" for Medicare providers are spelled out in detail in the Code of Federal Regulations for each type of health care provider (hospitals, skilled nursing facilities, home health agencies, clinics, outpatient physical therapy services and so forth).[1] In general, the regulations establish standards for staffing (level and qualifications), for safety and sanitary conditions, and for providing specified services (for example, laboratory or physical therapy services).

All institutional providers participating in Medicare or Medicaid are surveyed at least once per year to ascertain whether they meet the specified standards and, thus, may be certified to participate in the Medicare program.[2] Providers found not to be in compliance with one or more conditions of participation may be made ineligible for Medicare payment, depending on the nature and extent of the deficiencies.[3] The qualifications of individual physicians or suppliers are generally established through the various licensing systems governing their professional activities. As discussed in chapters 3 and 4, Medicare may exclude from the program physicians or suppliers found to be providing inadequate or substandard care or services.

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[1] See 42 C.F.R. 482. The actual certification process allowing participation was designed to be carried out at the state level. Section 1865 of the Social Security Act stipulates that any hospital accredited by the Joint Commission on the Accreditation of Hospitals (JCAH; now renamed the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)), an independent nonprofit organization, are presumed to meet Medicare conditions of participation.

[2] Responsibility for conducting surveys to determine continued compliance with Medicare conditions for participation was delegated to the states (Social Security Act, sec. 1864, 42 U.S.C. 1395aa). States are granted the authority to impose higher requirements for the certification of health care facilities than those set out by Medicare; in such cases, Medicare then imposes these higher state standards as a condition of participation (Social Security Act, sec. 1863, 42 U.S.C. 1395. Because hospitals can be accredited for up to 3 years, they may not be subject to full annual inspections. Hospital accreditation is discussed below.

[3] 42 C.F.R. 405.1905-07.

Questions about the ability of the survey and certification process to control quality of care problems have led to a series of changes in recent years. Revised conditions of participation for hospitals were published by HCFA in June 1986, the first substantial revisions to be implemented in over 20 years.[4] Among other changes, the new conditions for participation require hospital-wide quality assurance programs aimed at identifying and correcting patient care problems. This requirement applies to all medical and surgical services. To comply with this standard, hospitals must not only document the appropriate remedial actions taken in response to quality of care deficiencies, but must also document the outcome of those remedial actions.[5]

The Congress has also acted to strengthen certification standards because of concerns about inappropriate, as well as premature, discharges of Medicare patients from acute care hospitals and inappropriate placements of patients in posthospital care settings. In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986), the Congress required that participating acute care hospitals have in place a discharge planning program. OBRA 1986 also required the Secretary to arrange for a study of the standards of quality used for the conditions of Medicare participation for hospitals.

HCFA has also responded to a lawsuit brought on behalf of Medicaid nursing home residents concerning HHS' responsibility for assuring quality of care in skilled nursing facilities. The suit also affects Medicare facilities, because the survey and certification process is conducted jointly for the two programs. The Tenth Circuit Court of Appeals ruled that the Secretary of HHS had failed to fulfill a statutory duty to promulgate regulations that would enable him to determine whether Medicaid facilities are providing high quality medical care. To comply with the court's order, HHS developed a nursing home review process as part of the survey and certification program that includes a periodic survey of residents and focuses on the provision of services and resident care outcomes.[6] A study conducted by the Institute of Medicine raised a number of questions about the adequacy of the proposed nursing home resident survey, leading to additional refinement. HCFA has also developed programs to review patient care in home health agencies and hospices.[7]

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[4] The new conditions were intended "[t]o simplify and clarify Federal requirements, to provide maximum flexibility in hospital administration while strengthening patient health and safety, to emphasize outcomes rather than processes, to promote cost effectiveness while maintaining quality of care, and to achieve more effective compliance with Federal requirements" Federal Register, v. 51, n. 116, Tuesday, June 17, 1986, p. 22010.

[5] Medicare conditions for participation and JCAHO accreditation standards set out a general framework for the activities to be included in quality assurance, but do not specify the procedures or criteria to be applied in monitoring or evaluating quality. JCAHO is currently engaged in a project to develop outcome measures that could be incorporated into quality assurance review standards (see chapter 5). 42 C.F.R. 482.21. The regulations do not specify how, or how often, deficiency information is to be documented.

Withholding Payment for Unnecessary, Inappropriate, or Poor Quality Care

While conditions of participation are intended to assure that the structural conditions necessary for quality care are maintained, additional oversight of the services actually delivered to Medicare beneficiaries is also required by statute and regulations. Medicare bars payment for any items or services "which are determined . . . to be substantially in excess of the needs of individuals or to be of a quality which fails to meet professionally recognized standards of health care". Complying with this directive involves two related types of quality assessment activities: (1) identifying individual claims for reimbursement that do not meet Medicare criteria and standards for payment, and (2) identifying (and sanctioning, as appropriate) institutional providers, physicians, or other health care practitioners who are providing substandard care. The law and federal regulations assign these activities to three types of organizations: Utilization and Quality Control Peer Review Organizations (PROs), intermediaries (which process claims for services covered by Medicare part A hospital insurance, including inpatient hospital, skilled nursing home, home health, and hospice services), and carriers (which process claims for Medicare part B supplementary medical insurance, including physicians services and laboratory and diagnostic services). The HHS Office of the Inspector General provides additional oversight.

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[6] HHS presented the final rule on the new Medicare and Medicaid "Long-Term Care Survey" process as an improvement reflecting advances in the state of the art of quality assurance, stating in the background section: "Now that the current survey system has largely succeeded in improving the structural problems [in nursing homes], it has become clear that further improvements can be made in the quality of nursing home care by focusing more heavily on resident outcomes." Federal Register, v. 51, n. 114, Friday, June 13, 1986, p. 21551.

[7] Committee on Nursing Home Regulation, Institute of Medicine, Improving the Quality in Nursing Home Care (Washington, D.C.: National Academy Press, 1986). The 1987 Omnibus Budget Reconciliation Act (Public Law 100-203) includes provisions to implement a series of recommendations made by the Institute of Medicine, including a requirement that HHS evaluate the resident assessment protocols to be developed for use by both the skilled nursing facilities and state surveyors.

Peer Review Organizations

The Secretary of HHS is authorized to contract with PROs to review some or all of the professional activities of physicians and institutional and noninstitutional providers of health care services and items for which payment is made (in whole or in part) under Medicare. For those Medicare services for which they have review responsibility, PROs ensure that: (1) Medicare pays only for services that are "reasonable" and "medically necessary," as well as eligible for coverage under the Medicare statute; (2) the quality of such services meets professionally recognized standards of health care; and (3) the items and services covered could not, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient facility of a different type. The law does not define the terms reasonable, necessary, or appropriate. The Social Security Act explicitly precludes the federal government from exercising supervision or control over the practice of medicine.[a]

The regulations governing the first set of contracts with PROs required them to review only inpatient hospital care. These activities have since been expanded, primarily by OBRA 1986. Section 9343 of OBRA 1986 requires PROs to review all ambulatory surgical procedures specified by the Secretary of HHS (or, at the Secretary's discretion, a sample of selected procedures). Beginning in spring 1987, OBRA 1986 also requires PRO review of health care provided to Medicare beneficiaries enrolled in health maintenance organizations (HMOs) and competitive medical plans (CMPs). The act prohibits PRO reviews of physician services provided in office settings until January 1, 1989.[b]

OBRA 1986 further requires hospitals, skilled nursing facilities and home health agencies to maintain an agreement with PROs regarding review of services (other than the inpatient hospital services already required under Medicare prospective payment) and review of beneficiary complaints regarding quality of care. Finally, the act also includes a general provision requiring each PRO to devote a "reasonable proportion" of its activities to reviewing the quality of services in additional settings, including post-acute and ambulatory care settings.

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[a] Section 1801 of the Social Security Act (42 U.S.C. 1395) states "nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."

[b] Throughout this report, we use the term "PRO" generally to refer to peer review organizations authorized under title XI of the Social Security Act. This definition includes any medical peer review organization that contracts with HCFA for the review of the appropriateness or quality of Medicare services, including organizations contracting to review quality of care in health maintenance organizations and competitive medical plans. Under the first set of review contracts for HMOs and CMPs, all but one of the contractors also operates as a PRO reviewing inpatient Medicare services.

PRO contracts negotiated before January 1, 1987, do not reflect those 1986 provisions of OBRA which are effective for contracts entered into or renewed on or after January 1, 1987. Further, PRO executives have been told by HCFA that, even under the new legislative mandate, PROs will review skilled nursing facility or home health care only for Medicare patients who have subsequently been readmitted to acute care hospitals within 30 days of their initial hospital discharge and those initiated by beneficiary complaints.[10] Thus, with the exception of risk-based HMO and CMP services, most PROs are not currently reviewing health care services provided in skilled nursing facilities, by home health agencies, or in other subacute care settings covered by Medicare; their activities continue to focus primarily on inpatient hospital care.[11]

Section 1156 of the Social Security Act creates a mechanism for PROs to recommend sanctions, including exclusion from Medicare, against health care practitioners, hospitals, organizations, or agencies found to be providing services in a manner failing to meet Medicare requirements for medical necessity or professional standards of quality. PROs are obligated to initiate sanctions against providers who have failed to meet medical standards in a substantial number of cases, or been found to have grossly or flagrantly violated medical standards in one or more cases.[12]

The Consolidated Omnibus Budget Reconciliation Act of 1985 amended the Social Security Act by specifically authorizing PROs to deny payment for substandard care (as distinct from medically unnecessary or inappropriate). Although PROs already had the authority to deny payment for readmissions resulting from premature discharges or other inappropriate medical care under the existing legislation, the intent of the 1985 provision was to make it clear that PROs could and should deny payment to providers based upon findings of poor quality of care alone (independent of considerations of medical necessity or appropriateness of treatment). The law stated that denials were to be based on guidelines established by the Secretary of HHS. According to HHS, developing these guidelines has been difficult because of the complexity of the issues involved.[13]

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[10] HHS has noted in its advance comments on this report that outpatient department services are also included under the PROs' expanded mandate. (See appendix VII.)

[11] The Pennsylvania PRO began reviewing quality in posthospital settings effective July 1, 1987, and the Massachusetts PRO began posthospital care reviews in March 1988.

[12] The process of identifying patterns of quality of care or utilization problems among providers is discussed in chapter 4.

Carriers and Intermediaries

Carriers, who administer Medicare part B payments (primarily for physician and supplier services, paid from the supplementary medical insurance trust fund), are authorized by law to perform utilization reviews; that is, to determine if medical services provided to beneficiaries are medically necessary, appropriate, and promote the most efficient use of available Medicare health services and facilities. (See chapter 3, table 3.1, for a summary of carrier activities.) There is no requirement that specifically states that carriers should review claims for "quality of care" or "acceptable standards of care" in either the law or regulations governing Medicare.[14]

Intermediaries, who administer Medicare part A payments (primarily for inpatient hospital, skilled nursing facility, home health, and hospice claims from the Hospital Insurance trust fund), are also authorized by law to conduct utilization reviews.[15] They have responsibility for quality reviews of hospice care and for reporting to HCFA survey and certification officials any quality of care problems related to facility standards, staffing, and so forth, uncovered in the course of utilization reviews of home health care. In addition intermediaries perform "quasi-quality" reviews of skilled nursing facility claims and home health claims as part of their coverage reviews. In these reviews, intermediaries ascertain the level of care that beneficiaries require in order to determine if they meet

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[13] Draft rules under review state that payment would be denied for "substandard quality care that results in either of the following: (1) It results in an actual, significant adverse effect on the beneficiary, that is, patient management that results in unnecessarily prolonged treatment of the patient, complications in medical conditions, readmissions to the hospital, physiological or anatomical impairment, disability, or death; or (2) It presents an imminent danger to the health, safety, or well-being of the beneficiary or unnecessarily places the beneficiary in a high risk situation so as to constitute a gross and flagrant violation on which the PRO may proceed in accordance with 42 CFR 1004.50(a)(2)." (See appendix VII.)

[14] Section 1842 of the Social Security Act (42 U.S.C. 1395u) authorizes HHS to enter into contracts with carriers to make correct payments and assure correct utilization. The regulations found at 42 C.F.R. 421 reiterate the statutory provisions.

[15] Section 1816 of the Social Security Act (42 U.S.C. 1395h) authorizes HHS to enter into contracts with intermediaries to make payments to providers who nominate such entities and describes the responsibilities of these entities in terms of safeguarding utilization and making proper payments.

Medicare coverage criteria. Quality reviews of acute inpatient care are performed by PROs (see above), rather than by the intermediaries.

Intermediaries and carriers have legal authority to deny payment for Medicare claims and to recommend sanction of providers under the provisions of the Social Security Act barring payment for care determined not to be medically necessary or appropriate. They may not make determinations about medical necessity or appropriateness of services reviewed by PROs, but they are specifically granted authority to make coverage and reimbursement decisions (including denials of payment for services not meeting professional standards of quality) with regard to services that are not subject to PRO review.[16] Determinations by PROs regarding necessity, reasonableness, and appropriateness are conclusive under federal regulations.[17]

Monitoring Levels of Quality in Medicare Services

As the entities formally assigned responsibility for assessing the quality of care provided to Medicare beneficiaries, PROs are the primary source of information on quality issues. Under section 1160 of the Social Security Act, PROs are required to provide requested information to assist appropriate federal and state agencies in identifying cases or patterns involving risks to public health and in carrying out appropriate health planning activities.

Additionally, PROs must upon request provide aggregate statistical data (without identifying individuals) on a geographical, institutional, or other basis, reflecting the volume and frequency of services furnished, as well as demographic characteristics of populations reviewed.

Section 1161 of the Social Security Act requires HHS to submit annual reports to the Congress on the administration, cost, and impact of the PRO program. These reports are supposed to include data on the imposition of penalties and sanctions resulting from PRO review. There are no requirements in the Social Security Act or regulations for reporting to the Congress the types of problems leading to these penalties or sanctions, nor any requirements for the reporting of summary information on the types, extent, or resolution of quality or utilization problems detected by PROs. Similarly, there are no requirements in the Social Security Act for producing national information on intermediaries' and carriers' utilization or quality of care findings.

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[16] 42 C.F.R. 466.86(c). Prior to the establishment of the PRO program, we reported that some problems existed in assigning responsibility for sanctioning providers who overutilized Medicare services. Carriers' failure to initiate the sanctions process seemed to reflect HCFA's view that Professional Standards Review Organizations (PROs' predecessors) had basic responsibility for making determinations about medical necessity of all Medicare services, even though the review organizations were not actually reviewing all Medicare services. We recommended, in 1983, that HCFA make it clear to carriers that they could independently initiate the sanctions process based on the findings of their own medical peer review of providers, and HCFA concurred with this recommendation. GAO, Improving Medicare and Medicaid Systems to Control Payments for Unnecessary Physicians' Services (Washington, D.C.: GAO/HRD-83-16, February 8, 1983), pp. 42-7, 73.

[17] 42 C.F.R. 466.86.

Although there is no statutory requirement for reporting on Medicare quality of care levels, the Congress has asked for a series of studies that require the development of systematic information on a range of quality concerns. The Social Security Amendments of 1983 (Public Law 98-21), which established Medicare's prospective payment system for acute care hospitals, directed HHS to study the effects of the new payment system and possible expansions of prospective payment to other Medicare providers.[18] The Congress specifically mandated annual reports (starting in 1984 and ending in 1987) on the impact of prospective payment on classes of hospitals, beneficiaries, and other payers for inpatient services, and other providers.

OBRA 1986 extended the requirements for Medicare prospective payment system annual reports through 1989 and further required HHS to include information on the quality of posthospital care in the annual reports. In response to these and other congressional directives, HHS has initiated a variety of research projects, some of which are discussed in appendix VI of this report.

The Congress has also asked the Prospective Payment Assessment Commission to assume broad responsibilities for evaluating the impact of prospective payment on the American health care system.[19] Other questions about the effectiveness of ongoing quality review efforts are being addressed by congressional agencies. OBRA 1986 also included a provision requiring HHS to commission a study (by a unit of the National Academy of Sciences) to develop a strategy for quality review and assurance. These initiatives are discussed in chapter 7.

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[18] The prospective payment system provides for predetermined fixed payment rates for each hospital case, based on the diagnosis-related group into which each case falls.

[19] The commission is funded with appropriations from the Medicare trust funds. Its members are appointed by the Office of Technology Assessment. See chapter 7.

Conclusion: HHS Responsibilities for Assessing Quality of Care

The legal requirements for assuring quality of care in the Medicare program generally focus on structural requirements, denying Medicare payments to substandard providers, and identifying instances of inappropriate or unnecessary care. Independent systems have been devised for identifying problems in the structure of care and in the provision of Medicare-covered services to individual beneficiaries.

The Medicare legislation setting out HHS responsibilities does not require nationally representative information on levels of quality or problems related to quality of care in covered services or on the overall health care provided to program beneficiaries. There is no legislative requirement for integrated program-wide quality assurance in the Medicare program. However, congressional mandates to study the effects of payment reforms make clear the congressional expectation that information on the quality of care received by the entire Medicare population and subgroups within that population should be forthcoming. Developing such generalizable information from independent review activities that were designed as parts of a complex insurance payment system presents problems related to organization and data resources. These are described in chapters 3, 4, and 5.

Chapter 3

Carrier and Intermediary Medical Review

The review of the medical services for which Medicare reimburses providers is a multistage process, with only limited coordination across stages. In the course of processing Medicare insurance claims, carriers and intermediaries are required to review individual claims for appropriateness and necessity of the services provided. While the primary purpose of these reviews is to assist in coverage and payment decisions, they may also have implications for quality of care. In 1986, the medical review budgets for intermediaries and carriers were $32.2 million and $58.7 million, respectively.[1] Table 3.1 summarizes their basic review activities. A description of these activities, based on our analyses of program requirements and on our survey of carriers and intermediaries (see appendix III), is presented below.

Table 3.1: Overview of Intermediary and Carrier Quality-Related Review Activities

	Review of		
Reviewing organization	**Medicare services**	**Quality issues**	**Relevant data collected**
Carriers	Inpatient physician services Ambulatory physician services Durable medical equipment Diagnostic testing	Provision of unnecessary medical services (in number and kind)	Type of visit Procedures performed Patient age, sex, etc Dates of services
Intermediaries	Inpatient hospital Outpatient hospital Skilled nursing facility Home health Hospice Outpatient rehabilitation facilities Outpatient physical therapy	Provision of unnecessary medical services (in number and kind) Inappropriate setting (e.g., patient should be treated on an outpatient basis; home health patient requires more than intermittent care)	Diagnoses Procedures performed Patient age, sex, etc Dates of services, admission, discharge Plans of treatment

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[1] In this report, medical review is defined as any of the activities performed by or in cooperation with, and ultimately under the supervision of trained medical personnel, including nurses, qualified medical records technicians (generally, registered records administrators), and physicians for the purpose of determining the necessity, appropriateness, or quality of medical care.

Carriers

Carriers process close to 400 million Medicare bills per year. These represent the bulk of Medicare claims (in number of claims submitted), and for many beneficiaries, part B services are the only Medicare-covered services used in a given year. In order to identify inappropriate care and take action where questionable patterns of practice are found, both prepayment and postpayment reviews are required by HCFA.[2]

Prepayment Review

The primary goal of prepayment screening is to control previously identified utilization problems in a cost-effective way. Before claims are fully processed, carriers apply three categories of prepayment controls to examine types of claims which have been subject to abuse in the past or those of providers known to have questionable practice patterns.

Category I prepayment controls are denials of claims for services that are not covered by the Medicare program, including denials of claims for "medical necessity".[3] Category III screens are used by carriers to flag specific physicians or suppliers who have been identified for review based on the postpayment review process described below. Category II screens are carrier-developed or HCFA screens designed to flag claims for services that may be unnecessary, inappropriate, or abusive, and that therefore require medical review. Carriers have considerable flexibility in the design and application of Category II screens, but HCFA mandates that carriers use, at minimum, a specific subset of such screens.[4]

While all carriers are required to use the mandated prepayment screens, each carrier has to integrate the screens into its own system of computer editing and screening. Carriers can apply tighter parameters provided the HCFA regional office agrees. Therefore, it is not surprising that we found some carriers implementing screens that were not precisely the same as the screen described in the Carrier Manual. For example, a HCFA-mandated screen allows physicians to bill for two visits to a patient in a skilled nursing home during a patient's first week there, and one in each week thereafter; more visits trigger a review of the claims for necessity of care. One carrier has implemented the screen by flagging all cases where a physician bills for more than one skilled nursing facility visit to a patient per week, including the first week. Our survey also indicated that some screens appear to be implemented more loosely than stipulated.[5] There were also some differences in the procedure codes included under several mandated screens.[6] In some cases, the way that a screen has been implemented by a carrier may be more effective than the screen described by HCFA. That is, it may appropriately identify for review a larger proportion of cases where payment should be denied. It is also possible, however, that tighter parameters might discourage providers or physicians from providing services that are both appropriate and necessary.

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[2] HCFA was unable to provide us with figures on the number of part B claims reviewed by nurse or physician medical reviewers. Altogether, about 9 percent of part B claims are denied in whole or in part annually.

[3] For example, Medicare will not pay for cosmetic surgery, routine physical examinations, routine foot care, or routine eye examinations or refractions.

[4] For example, one mandated screen identifies cases in which physicians billed for more than 30 hospital visits to a beneficiary in a 3-month period. Others identify claims for more than 12 chiropractic visits per beneficiary per year, and so on. These screens are discussed in appendix IV.

The carriers' optional prepayment screens vary widely in complexity and in the types of utilization problems they address. Twenty-seven of the 34 carriers we surveyed provided us with lists of their prepayment screens. The number of optional screens ranged from 5 to 177. Four carriers described prepayment screens that use diagnosis as well as procedure codes to identify noncovered services, even though HCFA does not currently require diagnostic codes on part B claims. For example, one carrier has developed a list of diagnoses for which electrocardiograms are acceptable; if an approved diagnosis is not indicated on the claim, it is selected for prepayment review. The same carrier has also developed a list of acceptable diagnoses for fluorescence angiography. Other carriers reported using diagnosis codes in reviewing the appropriateness of other claims, including chest X-rays, computerized tomography scans, mammograms, and ambulance services.

Postpayment Review

The goals for postpayment utilization review are (1) to monitor the Medicare claims experience of all physicians, other providers, and suppliers and to acquire statistical data on their billing patterns; (2) to identify physicians whose utilization patterns differ for their locality or specialty; (3) to correct program abuse and overutilization of service by recovery of overpayments; (4) to prevent further abuse in utilization by educating providers; and (3) to identify situations where prepayment controls are necessary.

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[5] One carrier screen allows up to two chiropractic visits per month without review, instead of the 12 per year stipulated by HCFA. Another allows three "new patient" visits per 3 months without review, while the mandated screen flags all "new patient" visits billed after the initial visit.

[6] For example, the chiropractic screen allows 12 procedures from codes A-2000 to A-2999 per patient year; one carrier screen appears to flag only code A-2000. Other carriers appear to code the procedures used in the urology supply screen differently from the HCFA stipulations. We are currently examining carrier utilization screens as part of another GAO study.

The postpayment review process begins with the selection of a 3-percent sample of physicians and suppliers who exceed utilization norms for the greatest number of categories (for example, office, home, hospital, skilled nursing facility, and nursing home visits, injections, electrocardiograms, surgery, office lab services, X-rays, physical therapy, consultations, and other carrier-proposed categories). Physicians and suppliers who fall into this initial 3-percent investigation list are subjected to additional review to determine if other areas of their practices need to be examined.

Carriers first try to explain the abnormal practice patterns based on knowledge of local conditions or circumstances. Failing that, they initiate efforts to educate providers about their billing practices and provision of services. If these efforts prove unsuccessful, or fraud or abuse is suspected, an integrity review is performed, consisting of an examination of at least 15 beneficiary claims from each suspect category.[7] Consultation with the carrier's medical staff is solicited, if necessary. For integrity reviews triggered by suspicion of fraud, however, medical review is not required at this stage. Further, when integrity review findings are reported to HCFA, no distinction is made between abuse situations involving "propriety or medical necessity of services" and fraud situations where a concern could be "whether or not services were in fact rendered as billed."

If problems are confirmed during the integrity review, a full-scale review is conducted. This review could involve obtaining medical records from physicians, skilled nursing facilities, and hospitals, as well as contacting beneficiaries to verify services if medical records do not support billing or if a physician shows an abnormally high rate of home visits. The medical necessity and reasonableness of services and supplies are verified by carrier physician reviewers.

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[7] Overutilization is considered the most serious type of abuse to which part B services are vulnerable. Other types of abuse include, but are not limited to "excessive changes for services or supplies," "claims for services not medically necessary, or if medically necessary, not to the extent rendered," "breach of assignment" (violating Medicare regulations by billing patients on assigned claims for amounts exceeding the difference between the Medicare payment and the Medicare-approved charge), using a "separate schedule of charges for Medicare and non-Medicare patients," and "gang visits" (billing simultaneously for visiting several patients "without rendering any specific services to individual patients").

Providers who have been identified for further review are placed on the Physician/Supplier Action File. This file contains the names (and provider numbers) of providers who are under investigation for abuse and the action being taken against them. Only a small number of investigations related to utilization issues (as opposed to fraudulent or abusive billing practices) lead to official sanctions.[8]

National data for 1985, supplied to us by HCFA, indicated that seven sanctions finalized by the Office of the Inspector General related to utilization and 18 related to utilization were pending. The Carrier Manual also states that severe and longstanding problems with providers should be reported to PROs, peer groups, or other professional organizations capable of exerting corrective influence.

Quality-Related Activities

Although most carriers confine their quality-related review activities to identification of unnecessary or inappropriate care, 10 carriers reported using some screens specifically focused on quality of care in their review of part B claims. These screens are based on criteria developed by practitioner groups and peer review societies, practitioner and staff advisory boards, or medical policy committees, and in one case, the length-of-stay guidelines developed by the Commission on Professional and Hospital Activities.

Carriers also undertake special studies addressing topics of concern in their service areas. For example, one carrier conducted a study that identified abuses in the provision of dermatology, psychiatric, and anesthesia services.[9] Another example is a study of coronary bypass graft operations, which was contracted to a local university.[10] Special studies like this could be useful in monitoring quality of care in the Medicare program because they can be tailored to carrier-identified problems. Like basic review activities, however, they generally focus on issues of overutilization and the investigation of possible fraud, and not on underutilization or substandard care. In addition, these are one-time efforts, rather than continuing reviews.

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[8] Sanctions include fines and exclusion from the Medicare program.

[9] In one case, for example, an anesthesiologist did not provide direct, personal, and continuous supervision of a nonphysician anesthetist, and overpayment of $176,631 was identified.

[10] The main finding of the study was that as the volume of these operations at a particular facility increases, the length-of-stay and mortality rates decrease.

HCFA Evaluations of Carrier Medical Review

HCFA has instituted a system for assessing carrier (and intermediary) performance called the Contractor Performance and Evaluation Program (CPEP). Regional office staff conduct CPEP reviews, focusing on a set of "functional criteria," which in 1987, included "Payment Safeguards—Medical Review." Altogether, there were six criteria sets which were, in turn, broken down into 78 specific standards against which carrier performance was evaluated. Payment Safeguards—Medical Review accounted for eight standards.[11]

CPEP reviews focus, for the most part, on contract compliance and efficiency. In 1987, the first standard used to evaluate carriers' medical review activities was the cost-effectiveness of its medical review program. This standard was scored on a 10-point scale, with a 10 representing medical review programs that recovered $25.01 or more per dollar spent on medical review, and a 0 representing recovery of $1.99 or less.

A second standard addressed the accuracy of medical review determinations based on the proportion of coverage and documentation errors found in a sample reviewed by the regional office staff. Carriers were also evaluated on how well they implemented mandated prepayment screens and protocols for medical review, how well they identified part A claims that should be reviewed as a result of part B denials (see below), whether they complied with HCFA procedures for postpayment review, and whether they submitted accurate and timely reports to HCFA.

HCFA's standards for evaluating the accuracy of medical review reports include whether the carrier has analyzed how well mandated and carrier-developed screens are working. Regional office staff are specifically instructed to determine whether the carrier's annual medical review report contains specific recommendations for screening improvements. Carrier reports are also supposed to justify any carrier-generated screen for which less than 20 percent of suspended claims are actually denied. Thus, while HCFA requires that carriers assess their prepayment and postpayment screening systems, these assessments focus primarily on cost-effectiveness and success in eliminating payment for unnecessary or noncovered services.

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[11] The fiscal year 1988 CPEP criteria, issued after a draft of this report was provided to HHS for review, place more emphasis on carriers' compliance with medical review standards and the accuracy of medical review determinations, and somewhat less on cost-effectiveness. (See appendix VII.)

Intermediaries

Intermediaries process claims for inpatient hospital services and outpatient surgery, which are paid for prospectively, and for outpatient hospital services and subacute care services, which are reimbursed using retrospective cost-based payment methodologies. Their medical review activities focus on the necessity of the services rendered and the appropriateness of the setting in which services were provided. However, the need to coordinate the review of part A services over the course of patients' episodes of care is requiring intermediaries to take a more comprehensive view of quality issues.

Hospital Review

Because medical review of acute care inpatient claims is performed by PROs, intermediaries limit their hospital reviews (about 11 million bills per year) to questions of coverage, diagnostic coding, and verification of eligibility and copayment data. (See appendix V). The Medicare Code Editor identifies cases in which the principal diagnosis or the surgical procedure codes recorded on the hospital bill are "unacceptable"; that is, describe circumstances that influence an individual's health status but do not actually characterize his or her current illness or injury. For example, the editor program flags (1) cases where the disease or condition is described in unspecific terms, such as "family history of ischemic heart disease"; (2) cases with diagnostic codes indicating a manifestation of a disease rather than the disease itself, such as diabetic cataract; (3) cases with nonspecific codes, such as bone infection with no indication of the precise site; and (4) cases with procedure codes that are not covered by Medicare, such as percutaneous angioscopy.

The code editor program also flags 12 principal diagnoses that are "questionable"; that is, could indicate unnecessary hospital admissions (for example, diabetes without complications, elevated blood pressure without hypertension). For outpatient surgery claims, an analogous computer program sets out invalid codes, noncovered procedures, and questionable covered procedures (which are covered only under some circumstances; for example, a procedure performed for medical and not cosmetic reasons).[12]

Cases with "unacceptable" diagnoses are returned to the hospital for correction. Bills with "questionable" diagnoses continue through the intermediary bill processing cycle, but are referred to PROs for postpayment review. Intermediaries keep track of the coding of "nonspecific" operating room procedures, and when providers submit too many such codes (more than 10 percent of monthly bills), intermediaries contact them to determine whether there is a need for additional education regarding the use of the procedure codes.

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[12] Altogether, intermediaries processed about 44 million outpatient hospital claims, including all types of outpatient surgery, therapies, tests, and so on. Outpatient physical therapy bill review is discussed below.

In addition to the mandated medical review edits, intermediaries may employ optional screens to detect utilization problems. Our survey of intermediaries indicated, however, that most intermediaries do not use optional screens when reviewing hospital claims. (See appendix III.)

Skilled Nursing Facility Review

The Medicare skilled nursing facility benefit is designed to provide short-term posthospital skilled nursing care; it is used by only a small percentage of beneficiaries.[13] Intermediaries' medical review of skilled nursing facility admissions (about 800,000 bills per year) is intended to ensure that the skilled level of nursing care is necessary and appropriate and that beneficiaries are not prematurely discharged from acute care hospitals. Approximately 45 percent of all skilled nursing facility bills are reviewed by intermediary nurse or physician reviewers. Determining compliance with Medicare coverage criteria requires fairly extensive review of information on patients' conditions and care needs.

For all admissions to hospital-based skilled nursing facilities, the intermediary must request medical records and review every claim to make a determination about the medical necessity of the admission and appropriateness of the level of care. Where the admission is necessary but the appropriate level of care required is higher than that provided in these facilities, the intermediary must report the case to the HCFA regional office. For admissions to non-hospital-based skilled facilities, the intermediary must select at least 30 percent of admissions for medical review (or, under alternative review plans approved by the regional office, another sampling fraction that must include, at minimum, a 20-percent random selection). When a significant pattern of unnecessary admissions to a particular facility (over 5 percent) is noted over a calendar quarter, 100 percent of admissions to that facility are reviewed in the subsequent quarter.

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[13] The Medicare skilled nursing facility benefit is limited to individuals who need daily skilled nursing care or rehabilitative services following a period of 3 or more days of hospital care. In most cases, the admissions must take place within 30 days of hospital discharge. According to discharge data compiled by the Commission on Professional and Hospital Activities, about 8.5 percent of Medicare discharges were to skilled nursing facilities in 1984; the proportion of these stays actually covered by Medicare (as opposed to other payors), however, is not known. (Otis R. Bowen, M.D., Secretary of Health and Human Services, Report to Congress: The Impact of the Medicare Hospital Prospective Payment System, 1985 Annual Report, draft, 1987.)

To identify utilization and quality-related problems in skilled nursing facilities, intermediaries have developed a range of procedures and protocols which may include examination of diagnostic codes, hospital length of stay, nursing facility length of stay, or patient outcomes (such as readmissions to acute care hospitals or deaths). The identification of quality of care issues is typically a byproduct of the prepayment and postpayment reviews. There are no official guidelines for identifying premature hospital discharges, but if one is suspected, intermediaries are required to report it to HCFA. Intermediaries can report suspected premature discharges identified in reviews directly to the local PRO, but this is not required by HCFA. Intermediaries are instructed to report these cases to the HCFA regional office, which then is to report the cases to the PRO.[14]

Home Health Review

Like the nursing home benefit, the home health benefit is directed primarily at patients recovering from acute episodes and is used by only a small proportion of Medicare beneficiaries.[15] Medical review of home health claims (about 5 million bills per year) is designed to promote consistent coverage decisions and minimize payment for noncovered services.[16] Intermediaries review about 52 percent of all home health bills. The information for coverage determinations is drawn from the standardized plans of treatment that providers submit with the basic billing forms, but intermediaries may also request additional information or copies of medical records. Postpayment reviews are performed to ascertain whether plans of treatment and providers' medical updates match the information contained in patients' medical records. Annually, the entire medical records of 20 randomly selected beneficiaries per provider are reviewed on site to determine the accuracy of the information reported to HCFA and to identify inappropriate or noncovered care for which claims should have been denied. If reviewers find evidence of poor or questionable quality of care, they are instructed to report this information to the HCFA regional office.

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[14] This policy was clarified in a memorandum sent to HCFA regional offices on December 14, 1987. (See appendix VII.)

[15] According to the Commission on Professional and Hospital Activities, about 5.4 percent of 1984 Medicare discharges were reported by hospitals to be discharged to home health care; some of these may not have been to Medicare-covered home health care. (Otis R. Bowen, M.D., Secretary of Health and Human Services, Report to Congress: The Impact of the Medicare Hospital Prospective Payment System, 1985 Annual Report, draft 1987.)

[16] Medicare payment for home health care is limited to situations where the patient has an acute condition; covered services are limited to people who are confined to their homes under the care of a physician and in need of part-time or intermittent skilled nursing care or physical or speech therapy. When provided in conjunction with skilled nursing care, home health aides, occupational therapy, medical supplies, and the use of medical equipment may also be covered. The services must be furnished under a plan of care prescribed and periodically reviewed by a physician.

The intermediaries reported to us that they use a variety of optional edits or screens to identify possible utilization problems, such as screens that flag cases with high numbers of home health visits for particular diagnoses, claims for services that were previously denied, or claims indicating high costs for supplies. They do not generally employ screens specifically designed to identify quality of care problems.

Comprehensive Outpatient Rehabilitation Facilities Review

Comprehensive outpatient rehabilitation facility claims are reviewed in essentially the same manner as skilled nursing facility and home health care claims. Billing forms are examined to ensure that only services covered by the benefit are reimbursed and that these do not exceed the medical needs of the patient or do not represent a level of care (for example, maintenance therapy) not covered in a comprehensive outpatient rehabilitation facility.[17] Apart from evaluation visits (which are permitted, but not mandatory), all outpatient rehabilitation services must be furnished under a written plan of treatment. Intermediaries are required to review every claim that can be identified from the claim number as being provided by a comprehensive outpatient rehabilitation facility and determine whether the service provided is covered by the benefit, stipulated in the plan of treatment, and reasonable and necessary for treatment of illness and injury.[18] There are no instructions in the Intermediary Manual regarding the identification of quality of care problems in medical review of outpatient rehabilitation facility claims.

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[17] Covered services include speech, occupational, physical, and respiratory therapy; social and psychological services, drugs and biologicals which cannot be self-administered; and prosthetic and orthotic devices and training in the use of these devices. These services are covered only if they would be covered as an inpatient hospital service. They are not covered if they are determined to be unnecessary or not reasonable for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member. Also, there must be some potential for restoration or improvement of lost or impaired functions associated with use of the service.

[18] HCFA records do not distinguish outpatient rehabilitation bills so as to provide numbers of payments to comprehensive rehabilitation facilities. Altogether, HCFA processed about 6.3 million comprehensive outpatient rehabilitation facility, occupational therapy, and physical therapy claims in 1987; about 5 percent were subject to medical review. Identifying a comprehensive outpatient rehabilitation facility is complicated by the fact that these facilities may also be home health agencies or medical equipment suppliers.

Part B Intermediary Outpatient Physical Therapy Bill Review

Although guidelines for intermediary review of outpatient physical therapy claims have been developed and published in the Intermediary Manual, systematic screening of these claims has not yet been implemented.[19] HCFA guidelines issued in November 1986 would require intermediaries to apply 67 HCFA-developed screens to all outpatient physical therapy bills under Medicare part B that are submitted by skilled nursing facilities, hospital outpatient departments, and home health agencies that do not provide physical therapy in addition to home health services, or other outpatient rehabilitation agencies.[20] These screens are designed to ensure that payment is made only for services that are necessary or reasonable and that are provided by qualified skilled therapists.[21] The screens are based on diagnostic codes, duration and frequency of treatment, and date of onset of illness or symptoms.[22] Any bill failing a screen would be reviewed by the intermediary's medical review staff, preferably by physical therapists. HCFA also developed criteria for determining whether physical therapy services are covered. This involves reviewing a 10-percent sample of bills that pass all the initial screens. As with comprehensive outpatient rehabilitation facility claims, the emphasis is almost exclusively on the identification of unnecessary and noncovered services; there are no instructions in the Intermediary Manual regarding the identification of quality of care problems. HCFA plans to implement the guidelines (revised as necessary) in early 1988.[23] In addition, PROs will assume some responsibilities for reviewing outpatient therapies as part of the intervening care review conducted for readmission cases.[24]

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[19] See U.S. General Accounting Office, Medicare: Rehabilitation Service Claims Paid Without Adequate Information, GAO/HRD-87-91 (Washington, D.C.: July 1987).

[20] The screens do not apply to physical therapy furnished under home health plans of treatment or physical therapy services furnished by comprehensive outpatient rehabilitation facilities.

[21] A patient must be under the care of a physician to qualify for outpatient physical therapy and speech pathology services. A plan of treatment must set out the type, amount, frequency, and duration of the services to be furnished to the patient, and indicate the diagnosis and anticipated goals of the therapy. Like all Medicare services, outpatient therapy does not cover custodial care, routine services, or nonphysician services provided to a hospital patient that were not provided directly or arranged for by the hospital, or any other services generally excluded from Medicare coverage.

[22] For example, screen 2 identifies for review bills with a diagnosis of Parkinson's disease with more than 18 treatments in a 6-week period.

[23] Implementation of outpatient physical therapy guidelines was delayed when the Office of Management and Budget (OMB) determined that the guidelines should have been submitted through its regulatory review process. While the guidelines were undergoing OMB review, intermediaries were instructed that they could not request medical records for reviewing outpatient therapy claims. OMB clearance was obtained in October 1987, at which time intermediaries were informed that they could begin requesting medical records from physical therapy providers. However, implementation of the screening guidelines was suspended pending meetings between HCFA and physical therapy provider representatives to discuss the clinical significance and appropriateness of screen elements.

Hospice Review

Intermediaries' review of hospice benefits is unique in that they are explicitly charged with investigating quality of care. About 100,000 hospice claims were processed in 1987; of these, about 5 percent were reviewed by physicians or nurses. As part of their quality review activities, intermediaries make required home visits to hospice patients or their families. The patients visited are selected from lists of patients served by providers meeting specified criteria (for example, all new providers, all providers whose average cost per patient was less than $5,200, all providers who exceed the Medicare per patient aggregated cost cap of $7,898 during the period November 1, 1986, through October 31, 1987). Patients (or family members) are not required to consent to interviews, however.

The Intermediary Manual states that the interviews are intended to find out how well the hospice program is working in order to help current and future hospice patients. The manual suggests that interviewers inquire about the patients' experiences with the program, including why they elected to use the hospice benefit, what types of services they are receiving, whether other services are needed, their satisfaction with the care, whether the hospice has billed for any services, and how, in general, they feel about the hospice program (relative to the patients' treatment).

Intermediaries have also been instructed to check on specific complaints concerning hospices' delivery of services to make sure there are no misunderstandings and that patients' plans of care are being followed. If deficiencies are identified, these are to be reported to the appropriate oversight agency (for example, certification officials, HCFA inspector general, and so on). Deficiencies could include failure to follow the patient's plan of care, inappropriate discharges, underprovision of services, and failure to deliver services. Written narrative reports of all home visits, including all questions asked by the reviewer and respondents' answers, as well as descriptions of any problems identified, are sent to the HCFA regional office within 30 days of the visit. However, intermediaries do not routinely report any summary information on the type or incidence of quality of care problems identified in hospice medical reviews.

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[24] See appendix VII.

In addition to the quality-oriented home visits, intermediaries review hospice claims to ensure that the services provided were stipulated in the plan of care signed by a physician, that these services are necessary for the palliation or management of the beneficiary's terminal illness, and that the services were adequately provided and appropriately classified for payment purposes. The hospice benefit is designed to be primarily a home benefit. Home visits are categorized into three types ranging from relatively brief visits to continuous 24-hour-a-day care. All continuous home care hospice claims are subject to intermediary medical review. For these claims, plans of care and medical records are reviewed to determine whether the beneficiary needed and received continuous services (which are defined as more than 50 percent skilled nursing services).

Intermediaries review at least 20 percent of inpatient hospice claims, using plans of care, and medical records if necessary. In addition, intermediaries review all hospital admissions for hospice patients to determine whether the admission is related to the patient's terminal illness. Hospital care can be reimbursed for hospice patients only if the services were medically necessary and appropriate for the control of pain or acute or chronic symptom management as outlined in the patient's plan of care or if the care was for a condition not related to the terminal illness.[25]

Intermediaries also review all instances where beneficiaries give up their enrollment in the hospice program and return to regular Medicare coverage, which is termed a "revocation." All revocations are reviewed immediately prior to beneficiaries' receiving Medicare hospital, skilled nursing facility, or home health benefits for conditions related to their terminal illness, and during beneficiaries' last election period for hospice benefits. This review is designed to ensure that patients are not being coerced by providers into forfeiting hospice benefits, thus allowing providers to be reimbursed for the individual services that might not be separately reimbursable under the hospice benefit.

HCFA Evaluation of Intermediary Medical Review

Intermediaries, like carriers, are evaluated under HCFA's performance evaluation system. In 1987, the Payment Safeguards—Medical Review standards addressed seven aspects of intermediary medical review activities, including the cost-effectiveness of medical review, the level and accuracy of medical review determinations in hospital-based and free-standing skilled nursing facilities, home health and outpatient bills, and the timeliness and accuracy of intermediaries' calculation of scores to rank home health agencies using cost report data (used for selecting agencies for review).

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[25] Inpatient days are not supposed to exceed 20 percent of total hospice days.

The rating of performance levels is clear-cut for those standards focusing on cost-effectiveness and timely and accurate submission of reports to HCFA. In 1987, a benefit savings of $15.00 for every dollar expended in administrative costs qualified an intermediary for a top score of 10; all reports on benefit savings (payments denied or recovered) had to be no more than 4 days late for a top score on that standard.

Evaluation of skilled nursing facility, home health, and outpatient medical reviews focuses, first, on whether the intermediary has complied with HCFA guidelines for selecting cases for medical review (for example, all hospital-based skilled nursing facility claims, a 20-percent sample of free-standing skilled nursing facility claims, and so forth). The regional office evaluates the accuracy of skilled nursing facility, home health, and outpatient medical review determinations by sampling cases (ranging from 25 to 50 for skilled nursing facility and home health claims, depending on the volume of claims), which are then reviewed, using the HCFA instructions and guidelines. If there is a question about a case, the intermediary can request additional documentation from the provider. In 1987, the percentage of accurate determinations was translated into a 10-point scale; 95-percent accuracy (a score of 8 or more) was considered acceptable performance.

Like the performance evaluation system for carriers, the intermediary system does not explicitly address any issues related directly to the identification of quality of care problems.

Conclusions and Recommendations

Carrier and intermediary medical review could be improved in two ways. First, assessments are needed of the effectiveness of the current screening and review methods used by carriers and intermediaries in identifying possible quality of care problems.

For carriers, for example, it would be useful to determine whether screens and profiles that currently focus on physicians with aberrant billing patterns also effectively identify physicians providing substandard care. For intermediaries, it would be useful to determine the relative effectiveness of different screens or review protocols in identifying inappropriate care placements or premature discharges. This is particularly important given the wide variation in the numbers and kinds of screens being used and the lack of attention to quality of care issues in the performance appraisal of carriers and intermediaries.

Once HCFA established the validity and usefulness of current review methods it could then identify and adopt effective methods of focusing on quality and quality-related problems and drop ineffective ones. Developing the capacity to systematically assess alternative methods for screening and profiling would also increase the credibility of the medical review system as a whole. We have previously recommended that HCFA evaluate the costs and benefits of carrier postpayment utilization review operations.[26] Evaluations of intermediary and carrier activities focusing on quality of care are also important.

Recommendation

We recommend that the Secretary of HHS direct the Administrator of HCFA to assess the comparative effectiveness of carrier and intermediary screens and profiles as means to identify inappropriate and substandard quality care, as well as recover Medicare overpayments.

The second way in which carrier and intermediary medical review can be improved relates to the coordination of Medicare review activities. While carrier, intermediary, and PRO reviews are carried out independently, program requirements increasingly necessitate the development of systems for coordinating review findings. Currently, coordination focuses largely on decisions about coverage and eligibility for Medicare reimbursement to ensure coordinated determinations regarding denials of payment. There is, however, little coordination among these three sets of contractors on issues related to quality of care.

HCFA has developed a system called the "A/B Data Exchange," which allows intermediaries to notify carriers of hospital payments so that carriers can make sure that they do not pay for ancillary services included in Medicare hospital payment. This system also allows intermediaries to refer to carriers by computer link all hospital and skilled nursing facility denials based on medical necessity, appropriateness, or reasonableness. This enables carriers to determine whether physician services billed for these inpatient stays should be denied payment. When PROs determine that hospital payments should be denied (see chapter 4), the intermediary billing data are revised. PROs also inform carriers of inpatient payment denials, and of all partial or full reversals of denials.[27]

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[26] See General Accounting Office, Improving Medicare and Medicaid Systems to Control Payments for Unnecessary Physicians' Services, GAO/HRD-83-16 (Washington, D.C.: February 8, 1983), pp. 37-8.

When carriers receive a PRO denial notice for invasive surgical procedures found to be medically unnecessary, they automatically deny claims submitted by the surgeon and assistant surgeon. Carriers also automatically deny physician bills associated with nonmedically necessary "cost outlier" hospital stays (or portions of stays) denied by PROs.[28]

Carriers review physician claims for visits to beneficiaries in skilled nursing facilities if such stays have been totally or partially denied by the intermediary. The implementation of the 1985 Consolidated Omnibus Reconciliation Act provisions calling for mandatory prior approval by PROs for certain elective surgical procedures also requires direct coordination between PROs and carriers.

As was noted in the discussion of medical review activities, however, findings regarding quality of care per se are loosely coordinated, if at all. Neither information about quality-related problems found in carriers' reviews of physician bills for surgical or postoperative care, nor possible quality problems found by intermediaries in reviews of post-hospital care are automatically forwarded to PROs. Rather, summarized review findings are reported to HCFA (generally to the regional office), or the survey and certification authorities.

Carriers are required to notify PROs about severe or longstanding problems with providers which have led to formal reviews or sanctions, but carrier-PRO relationships are generally informal. In short, direct communication among claims processors about potential quality of care problems that do not involve denials of payment is essentially an issue of professional responsibility or discretion. Further, there are no formal guidelines specifying how HCFA regional offices coordinate the flow of quality-related information from intermediaries and carriers to PROs.

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[27] Carriers are required to execute written agreements with PROs clarifying the administrative details regarding coordination of denial information. Systems for coordinating information—in hard copy or through electronic data exchange—are worked out by the PROs and carriers.

[28] Cost outlier cases are unusually high-cost cases, which may qualify for additional payment. (See chapter 4.)

Recommendation

We recommend that the Secretary of HHS direct the Administrator of HCFA to develop formal guidelines to coordinate the systematic and timely reporting by carriers and intermediaries to PROs of possible problems with the quality of care provided in ambulatory and posthospital care settings identified in medical reviews. These guidelines should ensure (1) that intermediaries report directly to PROs as well as to HCFA all cases where possible problems of premature or inappropriate hospital discharge may exist, including cases where Medicare coverage for skilled nursing facility or home health services has been denied to patients who may nevertheless have extensive care needs, and (2) that information about possible quality of care problems uncovered by carriers is routinely shared with PROs.

It should be noted that one phrase in the recommendation was revised in response to comments received from HHS. (See appendix VII.) Specifically, we have clarified the part of the recommendation relating to possible quality of care problems in cases not meeting Medicare coverage criteria for posthospital care. Medicare does not deny coverage for posthospital care because patients require higher levels of care. Nevertheless, patients requiring extensive posthospital care may not meet Medicare coverage criteria for home health or nursing home services. If intermediaries are aware of quality of care problems in cases ultimately denied Medicare posthospital coverage, we believe they should notify PROs about them.

The cost of implementing guidelines for following up on suspected quality of care problems found in intermediary or carrier medical reviews would depend on the amount of additional review activity they generate. Given that only a small proportion of Medicare patients are discharged to home health or skilled nursing facility care, and that only a small percentage of these cases are denied by fiscal intermediaries, the increase in review volume due to intermediary referrals to PROs is likely to be small.[29] Coordination of carrier medical review with PRO review could potentially involve more cases. But coordinating mechanisms will be required in any case for the proposed expansion of PRO review to physician and ambulatory care services discussed in chapter 2. Our recommendation addresses a current need and will also be useful in facilitating the anticipated expansion of PRO review.

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[29] As noted above, some intermediaries are already routinely reporting possible premature hospital discharge placements directly to PROs; for these, there would be no additional cost.

Chapter 4

Peer Review Organizations

Peer review organizations, working with data provided by claims processors and from medical records, perform the most extensive medical review of the services reimbursed by Medicare. There are now two sets of these review organizations—Utilization and Quality Control Peer Review Organizations (PROs), responsible primarily for review of inpatient hospital care, and Quality Review Organizations (QROs), which began reviewing the quality of care provided in Medicare HMOs and CMPs in 1987.[1] In fiscal year 1987, the federal government spent about $155 million for PRO inpatient review activities. The estimated cost of medical review in the new quality review organization program for HMOs and CMPs for fiscal year 1989, the first full year of QRO review, is $7.2 million.

Table 4.1: Overview of Peer Review Organizations' Quality-Related Review Activities

	Review of		
Reviewing organization	**Medicare services**	**Quality issues**	**Relevant data collection**
Professional Review Organizations	Inpatient hospital services	Provision of unnecessary medical services (in number and kind) unnecessary readmissions and transfers	Number of cases denied payment for utilization and quality reasons
		Care not meeting professional standards	Number of cases failing quality, utilization screens, or physician reviews
		Adequacy of discharge planning and incidence of premature discharges	
	Ambulatory Surgical Centers[a]	To be determined	To be determined
	Posthospital care services[a]	To be determined	To be determined
	Physician services in office settings[b]	To be determined	To be determined
PRO Quality Review Organizations (HMO and CMP)	HMOs and CMPs with "risk" contracts	Inadequate access to appropriate care	Number of cases failing screens or physician reviews
		Care not meeting professional standards	
		Adequacy of discharge planning and incidence of premature discharges	

[a] Legislative mandate to be implemented 1988 and after

[b] Legislatively prohibited until January 1, 1989

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[1] Most organizations reviewing HMO and CMP care are also Medicare PROs (see below).

Table 4.1 provides an overview of these review activities. Descriptions of specific review responsibilities and methods are presented below. The information generated by these organizations and its usefulness for addressing quality of care is discussed in chapter 5.

Utilization and Quality Control Peer Review Organizations

PROs focus on a range of quality, utilization, and payment issues including (1) the reasonableness, necessity, and appropriateness of hospital admissions; (2) the completeness, adequacy, and quality of care provided; (3) the validation of diagnoses and procedural information that determines Medicare payment; and (4) the necessity and appropriateness of care for which payment is sought on an "outlier" basis.[2]

Selection of Cases for PRO Review

PROs use the Medicare Uniform Billing (UB-82) records, from the "Unibill" file generated by intermediaries as the basis for selecting cases for review. (See appendix IV.) Specifications for selecting those cases are included in individual contracts negotiated by the PROs with HCFA.[3] Under the second round of contracts (1986 to 1988) each PRO reviews:

- a random sample of 3 percent of discharges from each PPS (prospective payment system) hospital in its jurisdiction.[4]

And for all cases not falling into the 3-percent sample, each PRO reviews:

- all cases coded with diagnosis-related group (DRG) code 462 (rehabilitation), DRG 468 (unrelated operating room procedures), and DRG 088 (chronic obstructive pulmonary disease);
- all cases where claims have been adjusted (due to changes in billing information submitted by a hospital in a way which has resulted in a higher weight (higher cost DRG payment);

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[2] Under the Medicare program, cases that have an extremely long length of stay (exceeding average length of stay by a specified amount) or extraordinarily high costs (by a specified percentage or amount) are termed day and cost outliers, respectively. Additional payment is made for these cases.

[3] Because of variations in the Medicare hospital payment systems the requirements for PRO review in Maryland, New Jersey, Puerto Rico, the U.S. Virgin Islands, and Guam and American Samoa differ somewhat from the general PRO requirements. An additional requirement included in the 1986 scope of work was removed from PRO contracts in August 1987. Under this provision, PROs reviewed 10 percent of discharges or 1,200 discharges (whichever was greater) in the 3-month period selected by HCFA for the purposes of validating individually negotiated performance objectives related to reducing utilization or quality of care problems.

[4] Within this sample, for the first 6 months of each PRO contract, all cases with a hospital length of stay of 1 or 2 days are reported to HCFA separately.

- all readmissions within 15 days of discharge from a PPS hospital;
- all cases with one of nine specific principal diagnoses for which HCFA has mandated prepayment review;[5]
- all transfers from a PPS hospital to another PPS hospital, a 50-percent random sample of transfers to swing beds, a 50-percent random sample of transfers to excluded alcohol/drug abuse units; and a 50-percent random sample of all transfers to excluded psychiatric units (including all of certain types of psychiatric transfers);
- a 50-percent random sample of day and cost outliers (cases qualifying for additional DRG payment);
- 100 percent of cases where patients disagree with notices of noncoverage issued by hospitals, 100 percent of cases where the patient is liable for charges for services rendered after a hospital notification of noncoverage, and 10 percent of all other cases where notices of hospital noncoverage have been issued;
- all cases in which the hospital has determined that an admission was noncovered but that the patient required a covered level of care at some point during the hospital stay;[6]
- a random sample of 15 percent of discharges from PPS-exempt hospitals;
- all claims for extracorporeal shockwave lithotripsy; every elective case of cardiac pacemaker implantation and reimplantation (preadmission);
- all cases referred by the intermediary for determinations of medical necessity; and
- five selected surgical procedures (one of which is the required pacemaker review listed above), for preadmission review as part of the PRO's quality objective activities.[7]

These groups of cases selected for review reflect the variety of discrete utilization control and quality review tasks assigned to PROs. They are not designed to provide a system of case review focusing on the overall quality of care provided to Medicare beneficiaries. The pool of cases reviewed is, however, shaped to some extent by an initial baseline analysis constructed from the 3-percent random sample of discharges during the first 90 days of the contract period. After applying generic quality screens (described below) to each of the randomly selected cases, and verifying the screen findings (using physician advisors as necessary), each PRO constructs a baseline of "occurrence levels" (that is, screen failures) for each screen item. This information is then used in the process of negotiating with HCFA specific "target reductions"; that is, contract objectives designed to reduce particular types of quality problems.

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[5] The diagnostic codes (International Classification of Diseases, 9th Revision, Clinical Modification, known as ICD-9-CM) listed in the PRO manual for automatic prepayment review are 25000 and 25001 (diabetes mellitus without mention of complication, non-insulin dependent or insulin dependent); 3804 (impacted cerumen); 4011 (benign hypertension); 4262, 4263 and 4264 (left bundle branch hemiblock, other and right bundle branch blocks); 7962 (elevated blood pressure reading without diagnosis of hypertension); and 9999 (other and unspecified complications of Medical care, not elsewhere classified). These diagnoses are also identified in the Medicare code editor program edits performed by the intermediary. (See chapter 3.)

[6] Under Medicare regulations, hospitals are responsible for determining whether patients' care needs qualify for admission and for Medicare coverage during the course of their hospital stay, subject to review by a PRO to verify the hospitals' decisions.

[7] The Consolidated Omnibus Reconciliation Act of 1985 (Public Law 99-272) stipulated that PROs also be required to specify at least 10 elective surgical procedures to be subject to preadmission or preprocedure review for the purpose of requiring a second surgical opinion where appropriate. The regulations for implementing this requirement have not yet been issued.

In addition, HCFA has provided each PRO with lists of DRGs and hospitals identified as statistical "outliers." DRG outliers are those diagnosis groups for which use patterns and mortality rates in the PRO's area hospitals are significantly different from national norms; hospital outliers are those for which mortality and utilization rates appear to be significantly different than expected, after adjusting for a series of hospital and patient characteristics. PROs were required to verify which DRGs on the list merit intensified review and, in a similar process, which outlier hospitals' mortality rates indicated possible quality of care problems that warrant intensified review.[a] These outlier analyses, together with the baseline analyses of the generic quality screens, also contribute to PROs' negotiations with HCFA to establish specific review objectives. The negotiations are designed to occur during the first 150 days of the 2-year contract period and affect all cases reviewed during the remainder of the contract.

Altogether, the 3-percent randomly selected cases plus those listed above for targeted reviews are expected to make up about 26 percent of all Medicare hospital admissions. Nationally, there are about 11 million discharges per year. From July 1986, when the first PROs began operating under the second PRO scope of work, through May 1987, over 6 million cases were "reviewed" (that is, screened to determine whether medical review was necessary) by PROs. The volume of cases across PROs reflects both the staggered start dates (July through December 1986) for the contracts and population size differences. For example, in this period, about 28,000 reviews were reported from Maine; 140,000 from Wisconsin; 320,000 from Ohio; and 700,000 from New York.[b]

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[a] For some PROs, no outliers were produced by the HCFA analyses.

[b] HCFA, "Data Sources and Uses," prepared by Anthony J. Tirone, Deputy Director, Office of Medical Review, Health Standards Quality Bureau (Baltimore, 1987) attachment C, p. C21.

HCFA estimates that when the current contract cycle is complete in 1988, about 38 percent of the cases PROs identify for medical review will be those selected as the 3-percent random sample cases, plus cases selected for review as part of a follow-up on providers identified through the random case review.[10] Another 10 percent will be selected as part of each PRO's contract objectives, which reflect both quality and utilization concerns. The remainder will involve readmissions, outliers, transfers, preadmission reviews, specified diagnoses, hospital notices of noncoverage, validation of the payment category assigned to the admission, and specialty hospital reviews. These may involve issues related to quality of care.

Only in the case of random sample cases, however, is the identification of types and levels of quality problems the primary purpose of medical review. The majority of PRO reviews are triggered by possible coding errors, coverage, utilization, or payment concerns.

PRO Medical Review

All cases selected for review by PROs (both prepayment and retrospective) are run through five basic reviews: generic screen review, discharge review, admissions review, coverage review, and DRG validation. These reviews are performed by health care professionals, usually nurses or registered medical records administrators or technicians. Potential quality-related problems are most likely to be identified by the generic screens, discharge reviews and admissions reviews. When potential quality problems are identified, cases are referred to physician advisors employed by the PRO, who make definitive decisions.

PROs review the entire medical record for each case under review. These records generally include the face sheet, the physician's attestation statement, the physician's admission note, the discharge summary, the history and physical, physicians' progress notes, physicians's orders, lab reports, pathology reports, and nurses' notes.

Lab reports are particularly important in assessing the generic screen for abnormal results of diagnostic services (see below); nurses' notes about a patient's progress in learning to self-administer a particular type of medication or therapy may be useful in determining the appropriateness of discharge planning efforts. The photocopies of records reviewed by PROs, however, may not be entirely complete or legible, and some may therefore not include all the information the reviewers might want or need.

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[10] Through May 1987, of approximately 1,490,000 cases selected for review by PROs, about 186,000, or 12 percent, were initially chosen as 3-percent random sample cases, and about 393,068 (26 percent) had been selected for review under the category of contract objectives. Source: HCFA, "Data Sources and Uses," 1987.

Generic Quality Screens

HCFA's generic screens consist of six items (with subitems). Screen 1 focuses on adequacy of discharge planning; screen 2, on medical stability of the patient at discharge; screen 3, on unexpected deaths; screen 4, on nosocomial (hospital-contracted) infections; screen 5, on unscheduled return to surgery, and screen 6, on trauma suffered in the hospital, including major adverse drug or medication errors. The screens from the PRO scope of work are reproduced in figure 4.1.

Cases failing one or more screens are referred to PRO physician advisors unless the initial reviewer is able to determine that no quality of care issue exists. There are some exceptions, however. Failures of the discharge planning screen, falls resulting in trauma, and nosocomial infections need not be referred to physician advisors, although PROs are required to report numbers of screen failures.

When generic quality screens were introduced in fall 1986, little guidance was provided on their use. In the initial 6 to 9 months of use, there was wide variation in the incidence of screen failures and confirmed quality problems: in several PROs, less than 5 percent of cases failed any screen, while in others, more than 40 percent failed. The percent of confirmed quality problems found in cases with screen failures ranged from less than 5 to over 70 percent; about half of the PROs fell in the 20 to 50 percent confirmed failure confirmation range.[11]

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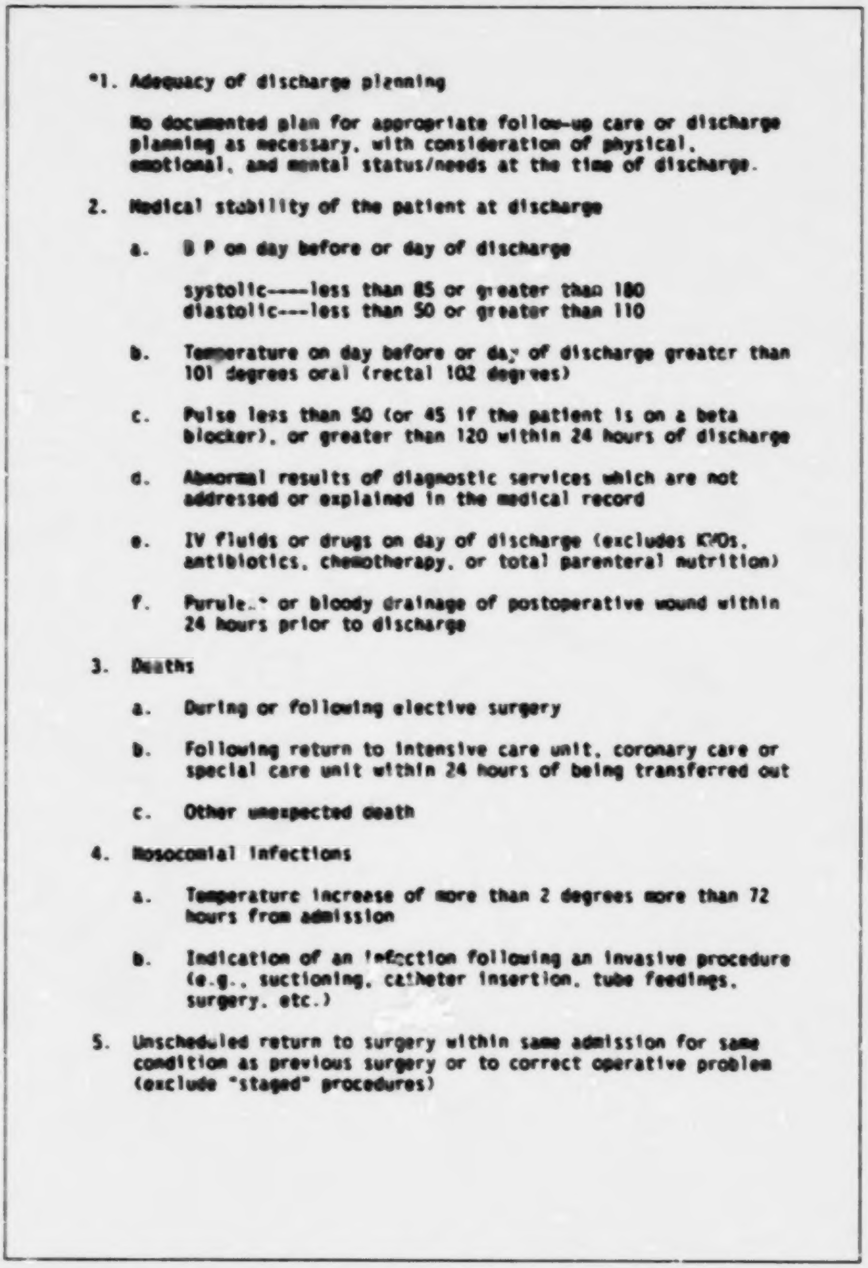
[11] Based on data accepted by HCFA as of May 6, 1987. Source: HCFA, "Data Sources and Uses," attachment E, p. E7. Because of problems in data reporting (which HCFA is investigating and trying to correct), the figures on generic screen failures should be viewed with caution. In addition, the data include quality problems found in focused reviews triggered by the 3-percent sample review, which—because these reviews are designed to concentrate on providers suspected of having problems—would tend to inflate the incidence of quality problems identified. Therefore, even though the data reported above include reviews of the 3-percent random sample, they are not a reliable means of comparing PRO performance or the incidence of quality problems across states, nor can they be used to make projections about the rate of quality problems nationwide.

Figure 4.1: PRO Generic Quality Screens



*1. Adequacy of discharge planning

No documented plan for appropriate follow-up care or discharge planning as necessary, with consideration of physical, emotional, and mental status/needs at the time of discharge.

2. Medical stability of the patient at discharge

   a. B P on day before or day of discharge

      systolic----less than 85 or greater than 180
      diastolic---less than 50 or greater than 110

   b. Temperature on day before or day of discharge greater than 101 degrees oral (rectal 102 degrees)

   c. Pulse less than 50 (or 45 if the patient is on a beta blocker), or greater than 120 within 24 hours of discharge

   d. Abnormal results of diagnostic services which are not addressed or explained in the medical record

   e. IV fluids or drugs on day of discharge (excludes KVOs, antibiotics, chemotherapy, or total parenteral nutrition)

   f. Purulent or bloody drainage of postoperative wound within 24 hours prior to discharge

3. Deaths

   a. During or following elective surgery

   b. Following return to intensive care unit, coronary care or special care unit within 24 hours of being transferred out

   c. Other unexpected death

4. Nosocomial infections

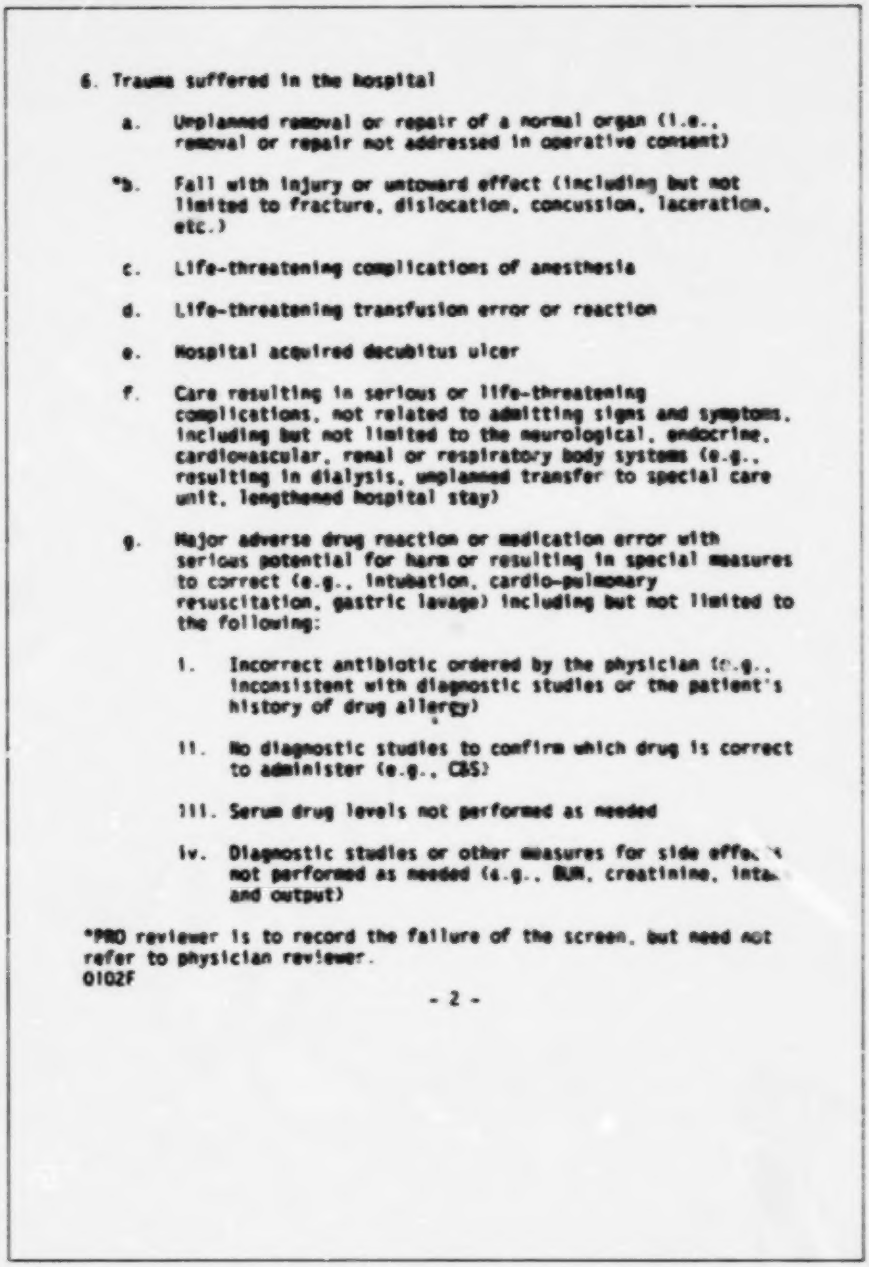
   a. Temperature increase of more than 2 degrees more than 72 hours from admission

   b. Indication of an infection following an invasive procedure (e.g., suctioning, catheter insertion, tube feedings, surgery, etc.)

5. Unscheduled return to surgery within same admission for same condition as previous surgery or to correct operative problem (exclude "staged" procedures)

Source: Health Care Financing Administration, 1987

Figure 4.1: (Continued)



6. Trauma suffered in the hospital

   a. Unplanned removal or repair of a normal organ (i.e., removal or repair not addressed in operative consent)

   *b. Fall with injury or untoward effect (including but not limited to fracture, dislocation, concussion, laceration, etc.)

   c. Life-threatening complications of anesthesia

   d. Life-threatening transfusion error or reaction

   e. Hospital acquired decubitus ulcer

   f. Care resulting in serious or life-threatening complications, not related to admitting signs and symptoms, including but not limited to the neurological, endocrine, cardiovascular, renal or respiratory body systems (e.g., resulting in dialysis, unplanned transfer to special care unit, lengthened hospital stay)

   g. Major adverse drug reaction or medication error with serious potential for harm or resulting in special measures to correct (e.g., intubation, cardio-pulmonary resuscitation, gastric lavage) including but not limited to the following:

      i. Incorrect antibiotic ordered by the physician (e.g., inconsistent with diagnostic studies or the patient's history of drug allergy)

      ii. No diagnostic studies to confirm which drug is correct to administer (e.g., C&S)

      iii. Serum drug levels not performed as needed

      iv. Diagnostic studies or other measures for side effects not performed as needed (e.g., BUN, creatinine, intake and output)

*PRO reviewer is to record the failure of the screen, but need not refer to physician reviewer.
0102F

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In a memo dated March 1987, actually issued in May 1987, HCFA modified PRO contracts to clarify and improve the generic screen component of peer review. This modification included a new 7-page "Generic Quality Screens Guidelines." For each screen, the guidelines indicate exclusions, that is, cases which need not be screened (for example, most patients who have died in the hospital need not be subject to other screens, because all deaths following elective surgery or unexpected deaths are flagged by screens specifically designed for that purpose).

The guidelines also specify the data sources reviewers may wish to consult to obtain relevant information. In screening medical stability at time of discharge, for example, reviewers are directed to progress notes, nurses' notes, graphic charts, and discharge summaries in the medical records. Finally, the guidelines include explanatory notes intended to clarify the intent or terminology used in some of the screens. For example, the explanatory note for the medical stability screen states that vital signs should be screened for all patients, including those in hospitals or facilities that do not routinely take vital signs (such as psychiatric hospitals), but that if vital signs are not ordered, the case should not automatically fail the screen. The specificity of the explanatory notes varies. PROs are permitted to add additional, locally developed quality screens to the six mandated screens, but they may not change the intent of the standard screens. Evidence regarding the usefulness of the new guidelines in aiding interpretation of the screens is not yet available.

Discharge Reviews

Two types of premature discharges are actually identified and recorded by PROs.[12] First, PROs identify premature discharges in their review of readmissions to acute care hospitals and transfers to other acute care facilities. Under Medicare regulations, payment for an initial admission is denied when it is determined that a patient had to be readmitted or transferred because the patient was not medically stable at the time of the first discharge.[13] Second, PROs record and report the number of premature discharges identified in their "discharge review" activities, which include, but are not limited to, application of generic quality screen 2. Each PRO has developed guidelines for identifying premature discharges. These guidelines are reviewed by HCFA, but it has not provided guidance in developing the screens beyond that in the Generic Quality Screens Guidelines.

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[12] Premature discharges are defined in the PRO scope of work as "discharges (other than those where the patient left against medical advice) where, in the opinion of the PRO physician reviewer, the patient was not medically stable and/or where discharge was not consistent with the patient's need for continued acute inpatient hospital care."(Scope of Work, April 1986, p. 12.)

[13] PROs focus on readmissions occurring within 15 days of the discharge; however, there is no time limit for denials for initial admissions that culminate in premature discharges and subsequent readmissions.

Admissions Reviews

The primary goal of admissions review is to reduce unnecessary admissions or procedures. PROs review all cases with specified ICD-9-CM principal diagnoses that are likely to be indicative of unjustified hospital admission. This is accomplished by the basic editing procedures performed by all PROs (which serve as checks on the Medicare edits performed by intermediaries). Admission review also occurs as part of the review of both day and cost outlier cases; in reviewing DRGs and procedures mandated for postpayment review by all PROs; and in review for admissions targets (reductions in unnecessary admission for specific conditions or procedures) negotiated as part of each PRO's objective-setting process. PROs report total numbers of admission denials in three categories: coverage (for example, where the admission is denied due to Medicare coverage requirements); utilization (for example, discharges, or proposed admissions for preadmission review, where the admission was found to be medically unnecessary or inappropriate); and denials of admissions owing to circumvention of prospective payment regulations (admissions for care that could have been provided during a previous admission).

PRO Profiles of Providers and Physicians

PROs routinely create from their data bases profiles that can be used to identify hospitals and physicians with aberrant patterns of billing for Medicare services. These profiles provide a means of focusing PRO review activities. The variables that reflect potential hospital quality issues include cases which fail admission and quality objectives, mortality rates, cases which fail generic screens, and readmissions within 15 days of discharge. Physician profiles reflect claims denial rates, mortality rates, applicable review findings on quality and admissions review (also required for hospital profiles), and length of stay for premature discharges. The general guidelines for determining whether a pattern of utilization or DRG coding problems warrants intensified review of hospitals is 5 percent, or six cases, exhibiting errors (defined as inappropriate admissions or transfers, errors in approving outlier stays, or incorrect DRG coding).[14] For quality of care issues, however, the threshold for initiating each stage of corrective action, including intensified review, has been developed by each PRO as part of the quality intervention plan included in its contract. Quality intervention plans are evaluated by HCFA, but HCFA does not currently prescribe standard trigger levels to be used by all PROs.[15]

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[14] The level of scrutiny given hospitals under intensified review depends on the type of error that triggered such review. For example, when hospitals are placed under intensified review for reaching or exceeding error thresholds for unnecessary or inappropriate hospital admissions, PROs can either review a 50-percent random sample of admissions or add a 100-percent review of a subset of cases in addition to the normal nonintensified review for a calendar quarter; review levels are increased if error rates in excess of the trigger levels persist.

PRO Corrective Actions

When PROs find patterns of quality problems associated with individual physicians or hospitals, and these problems cannot be explained or rectified through informal discussions, PROs are required to initiate corrective actions. These may include requiring a physician to participate in a continuing education program; changing the timing of reviews (for example, requiring predischarge reviews for physicians responsible for high rates of premature discharges); placing a physician or facility under intensified review; or initiating formal sanctions, which can lead to the imposition of monetary penalties by the Inspector General or exclusion from the Medicare program (under the same administrative rules governing sanctions recommended by carriers or intermediaries).

PROs initiate formal sanctions only when informal or other corrective actions have failed to change provider or practitioner practice, and if there is a "substantial violation" or a "gross and flagrant" violation of medical practice.[16] Through December 1986, approximately 6,500 hospital discharges involving 2,500 providers had been identified by PROs as having potential quality of care or utilization problems. Over 97 percent of these cases were resolved through discussions and meetings between the PROs and providers or practitioners. Through September, 1987, 138 cases had been referred to the Office of the Inspector General for review and further action. Of these, 54 resulted in HHS' excluding a provider or practitioner from Medicare. In another 25 cases, monetary penalties were imposed (24 physicians, one facility). Of these 79 cases where penalties were imposed, 62 involved "gross and flagrant" violations of statutory standards. As of October 1987, 13 referrals were under review by the Office of the Inspector General.[17] Nationally, nearly 7,000 hospitals and 450,000 physicians are reviewed by the Medicare program.

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[15] The draft regulations for denying payment for substandard care (see p. 21) establish a standard threshold for intensified review. if five percent (or 6 cases) of the total reviews completed during the calendar quarter are found to have denied days, intensified review would begin. More complex guidelines and prescribed interventions for triggering corrective action, based on a system that takes into account the severity of the quality problems identified, are also included in the proposed scope of work for the next set of PRO contracts.

[16] A gross and flagrant violation is defined as "a violation of an obligation which has occurred in one or more instances and which presents an imminent danger to the health, safety, or well-being of a Medicare beneficiary in high risk situations such as risk of substantial and permanent harm." A substantial violation is defined as "a violation of an obligation which has occurred in a substantial number of discharges in which care has been provided in a manner that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care."

Validating Medical Determinations by Peer Review Organizations

HCFA has developed two sets of activities to monitor the medical review activities of PROs: an internal PRO Monitoring Protocol and Tracking System (PROMPTS-2), and review by an independent contractor called the SuperPRO.

PRO Monitoring Protocol and Tracking System

The PROMPTS-2 system is being used to evaluate PROs under the second set of PRO contracts (1986-1988). It is a new system, and little is known about how well it is working.[18] The system focuses on whether PROs have fulfilled their contractual obligations. As part of this oversight, HCFA regional staff re-review samples of PRO cases to determine if individual screens, review procedures, and so forth are being applied correctly. The HCFA staff performing these reviews generally are registered nurses, although in some regions the reviews are done by analysts working under the supervision of physicians and nurses. Two PROMPTS-2 reviews are required for each PRO during the course of its 2-year contract. Regional office staff select random samples of cases from various review categories, for example, cases from the 3-percent random sample, readmissions, transfers, outliers, intermediary referrals, and so forth. The PROMPTS-2 instructions specify that the minimum number of cases to be re-reviewed generally is 25 cases per category, but if the PRO has reviewed relatively large numbers of cases, somewhat larger re-review samples (up to 80 per category) will be selected.[19]

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[17] Testimony of Richard P. Kusserow, Inspector General of the Department of Health and Human Services Before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations On the Peer Review Organization Process, October 20, 1987.

[18] The PROMPTS-2 system reflects extensive refinements to the original PROMPTS system used to evaluate the first set of PRO contracts. Problems with the first PROMPTS reviews are discussed in GAO/HRD-88-13, *Medicare: Better Controls Needed for Peer Review Organizations' Evaluations*, Washington D.C., October 1987.

[19] HCFA PROMPTS-2 instructions include a standard sampling procedure that calls for review of cases using the following data: When the universe size is 1-25, then the minimum sample is all; when the universe is 26-90, then the sample is 25; when the universe is 91-280, then the sample is 40; 281-3,200, then 60; over 3,200, then 80. In addition, HCFA requires that regional offices not using the standard methodology sample a minimum of 25 from the 3-percent random sample cases and 15 from the other categories.

Regional office staff record the results of their re-reviews, indicating on a summary form the frequencies and the percentage of cases overall for which they disagreed with initial PRO determinations regarding admission, coverage, discharge, generic quality screen, and DRG validation. These disagreements are recorded as "deficiencies" on a PROMPTS-2 summary form, and are also used to compute summary scores characterizing PRO performance. For example, PROMPTS-2 asks these questions about PROs' use of the generic quality screens:

> "Does the PRO correctly review all cases against HCFA Generic Quality Screens and identify potential quality problems?
>
> "a. Does the PRO physician advisor review records failing one or more screens (excluding the exceptions listed in the generic quality screens, i.e. discharge planning, nosocomial infections and trauma due to a fall)?
>
> "b. Does the PRO initiate appropriate interventions for identified quality issues?
>
> "c. Does the PRO initiate a data base on cases which fail each quality screen to enable it to analyze which element(s) of each screen are failed, and to focus interventions [categorized] by provider, practitioner and DRG?"

The generic quality screens review is one of 21 medical review activities covered by PROMPTS-2. An additional six questions address the PROs' interventions for quality of care issues. The yes/no answers to the questions describing PROs' performance on the generic screens constitute four of more than 200 yes/no questions covering a set of program review areas; for example, meeting program objectives, medical review activities, data systems, and management controls. Reviewers report summary scores for each review area, as well as an overall determination about each PRO's performance.

The criteria provided to reviewers for determining whether the PROs are performing adequately, are not, in some instances, clearly defined. For example, PROMPTS-2 asks the reviewer to determine if the PRO has effectively identified areas where quality of care problems call for some form of active PRO intervention, whether the PRO promptly resolved the problems, and whether this resolution was appropriate. The terms "effectively," "promptly," and "appropriate" are not defined for reviewers.[20] This lack of specificity introduces considerable room both for judgment on the part of the individual reviewer, and inconsistency across reviews, and especially across regional offices.

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[20] GAO/HRD-88-13, Medicare: Better Controls Needed for Peer Review Organizations' Evaluations, Washington, D.C., October 1987, p. 31.

The PROMPTS-2 system may alert HCFA to possible problems with a PRO's performance with respect to particular aspects of its medical review activities or contract compliance. It is not intended, however, to generate information on the types of quality problems that PROs are detecting, or failing to detect.

Superpro Review

The SuperPRO is a major effort by HCFA to evaluate the PRO program. Beginning in June 1985, SysteMetrics, Inc. contracted with HCFA to evaluate the performance of all 54 Professional Review Organizations by re-reviewing a sample of their cases. The first SuperPRO contract was extended through August 1987; a new contract involving essentially the same review system will cover the next 16 month period, for a total contract award of about $4 million over a 4-year period. The basic objectives of SuperPRO review as stated in the request for proposals are

> "1. To validate the determinations made by PROs, specifically on admission review, discharge review, and DRG validations.
>
> "2. To validate the medical review criteria being used by nonphysician reviewers for admission review;
>
> "3. To verify that nonphysicians are properly applying the PRO's criteria for referring cases to physicians for review; and
>
> "4. To identify quality issues which should have been addressed by the PRO (use the screening criteria)."

The SuperPRO reports are considered "advisory," and their decisions do not directly affect the payment of claims for Medicare services. That is, if the SuperPRO finds that a particular claim should have been denied by a PRO, this finding does not automatically result in the retroactive denial of the claim. HCFA is responsible for reviewing SuperPRO findings and taking any necessary actions to follow up on problems identified by the SuperPRO.

For each of the two review cycles included in the 1987-1989 scope of work, the SuperPRO will receive the medical records for a sample of approximately 400 hospital admissions per PRO and make an independent judgment on each. Thus, the total number of cases to be reviewed under the new SuperPRO contract is about 40,000 for the two cycles.

The SuperPRO draws a representative sample from a list of all the cases that the PRO reviewed in each of two specified 6-month periods. Cases for which the PRO has not completed reviews for both utilization and appropriate DRG coding are excluded from the sample, as are cases reviewed by the PRO as day of stay or cost outliers and admissions and transfers to PPS-exempt facilities.

Following the basic PRO model, the SuperPRO uses its own team of nurses or medical records technicians to pick out cases warranting physician review, and then draws on physicians recruited from across the country by a subcontractor to make final determinations on the medical necessity of the admission, the accuracy of the DRG coding, the appropriateness of the hospital discharge, and the quality of care provided. The SuperPRO uses the generic quality screens that HCFA requires of all PROs; it reviews cases for premature discharges using the screens applied by each individual PRO.

In principle, the SuperPRO bases its review on the same information, as well as the same formal criteria, that the PRO used in the initial review. The SuperPRO receives copies of the hospital medical records for all cases sampled.[21] In some states this may include nursing notes; in others, not. The one area where the SuperPRO has fewer data to work with than PROs concerns reviews of readmissions within 15 days. In these cases the PROs have access to both sets of hospital admissions, but the SuperPRO only receives the record for the second admission.

The SuperPRO compares the findings of its evaluators on quality of care problems to those found by the PRO.[22] Physician determinations regarding quality problems are categorized and reported using a three-level severity scoring system: level 1 problems are those with no potential for significant adverse effect to the patient; level 2, those with potential for significant adverse effect for the patient; level 3, problems with actual significant adverse effect to the patient.

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[21] It is each PRO's responsibility to locate, copy, and ship these records to the SuperPRO, along with copies of the PRO's own worksheets relating to each case. Initially, the SuperPRO experienced problems because in many cases these records arrived late, or were incomplete and had to be re-requested. The SuperPRO also had problems deciphering the PRO worksheets. In response, the SuperPRO asked the PROs to fill out a specially designed abstraction sheet for each sampled case with key information, such as the PRO's final determination on the proper DRG assignment.

[22] Quality problems related to premature discharges are not included in SuperPRO reports to HCFA.

To date, the SuperPRO has not attempted analyses that would draw comparisons across PROs or from one 6-month period to the next. Because the SuperPRO only checks those cases that the PROs have actually investigated, and does not address the issue of how cases are selected for PRO review or whether cases not selected for review should have been, the SuperPRO reviews do not provide information about either the overall incidence of quality problems in the Medicare population or the overall effectiveness of PROs in identifying and rectifying those problems.

Cases with quality (or other problems) identified by SuperPRO physician reviewers are submitted in a preliminary report to the PRO under review. This gives the PRO a chance to go over the cases and decide if it wants to appeal the SuperPRO judgment by providing more information or additional explanations. Frequently PRO appeals lead to reversals of decisions in favor of the PRO.[23] Moreover, through this process, the PRO finds out what kind of cases are likely to be questioned by the SuperPRO. PROs can then deal with these cases differently; for example, by providing better documentation or adopting interpretations of Medicare coverage guidelines or operational procedures more compatible with the SuperPRO's.

The SuperPRO informally validates its system for judging quality, medical necessity, and DRG assignment through experience rather than explicit testing. For example, when a PRO objects to the SuperPRO's decision, the case generally is given to a second physician to review. Unless the second physician supports the initial SuperPRO position, the PRO's objection is accepted. The patterns of acceptance and rejection are monitored. For the initial nurse and medical records technician reviews performed by the SuperPRO, the pattern of physician referrals by individuals reviewing the same PRO are monitored manually, and those deviating from the norm for referrals for that PRO are supervised more closely.

In its proposal to HCFA for the first contract, the SuperPRO outlined a more elaborate process to test inter-rater reliability through a random re-review of a 5-percent sample of cases, but implementation was delayed by limitations in their microcomputer system. A physician review of a sample of all cases examined by the nurses, including those not referred, was considered and rejected on cost grounds. HCFA has designed a system for overseeing SuperPRO evaluations and case reviews. This includes the selection of a sample of SuperPRO cases that HCFA examines to verify their accuracy. During the first SuperPRO contract period, the results of this examination were reported to the SuperPRO informally, and no written report was prepared.

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[23] Although total SuperPRO reversal figures are not currently available, HCFA figures for 51 of 54 PROs for a review cycle completed in 1987 showed a rate of reversal of SuperPRO findings with regard to quality of care to be about 20 percent. These were cases where problems were found by the SuperPRO but had not been reported as problems by the PRO and, upon reconsideration, were determined not to be problems after all.

Quality Review in Medicare HMOs and CMPs

Contracts to review quality of care in Medicare HMOs and CMPs were still being negotiated in September 1987; reviews are, however, retrospective to April 1, 1987.[24] By law, review responsibilities were assigned automatically to PROs in 25 states, and PROs have been awarded contracts competitively in all but two of the remaining states.

The request for proposals for HMO and CMP peer reviewers (referred to here as quality review organizations, or QROs, to differentiate their HMO and CMP functions from those related to PPS inpatient reviews), issued in March 1987, outlined an extensive set of activities. These activities are divided into three basic sets: initial analyses, specific activities, and intensified reviews of providers found to have substantial problems (similar to intensified review by PROs, carriers or intermediaries).

Initial Analyses

Initial analyses of HMOs and CMPs are performed only for plan's requesting "limited review" status (see below). They consist of review of the plan's internal quality assurance program and a re-review of a sample of Medicare cases previously reviewed by the HMO or CMP. The criteria used to determine the adequacy of the internal quality assurance activities are not formally specified, but suggested criteria closely parallel the criteria HMOs and CMPs must meet in order to qualify as TEFRA HMOs and CMPs. These criteria include, for example, whether the HMO or CMP reviews individual cases of patient care; whether the HMO's or CMP's quality assurance process includes physician review of medical records; whether final decisions about quality of care are made by physicians; whether the review includes all settings in which care is provided (for example, hospital, inpatient, posthospital and ambulatory); and whether corrective actions are implemented as a result of negative review findings. The number of cases to be re-reviewed and the depth of that review is left to the contractor, subject to HCFA approval.

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[24] Quality reviews are performed for HMOs and CMPs providing Medicare services for a fixed per capita fee under section 1876 of the Social Security Act as amended by the Tax Equity and Fiscal Responsibility Act of 1985 (TEFRA).

If a plan has a quality assurance program in place that demonstrates the capacity to identify and correct quality problems, it is then placed in a "limited review" category, which means that only a small proportion of cases are subject to QRO review (see below) as well as a re-review of cases the HMO or CMP reviewed as part of its internal quality assurance program. Plans not meeting these standards, and plans that choose not to undergo initial reviews are placed in a "basic review" category, which requires closer scrutiny by the QRO. HMOs and CMPs found to have substantial deficiencies in reviews of quality of care can also be placed in the "intensified review" category, which entails extensive review. Results of these initial analyses are not yet available.

Specific QRO Activities

The QRO scope of work includes seven categories for which some or all cases must be reviewed by the contractor:

- reviews triggered by hospital admission diagnoses of one of 13 specific medical conditions which could indicate poor- quality ambulatory care (see figure 4.2.);
- "focused ambulatory care reviews" to be developed by the contractor subject to HCFA approval;
- a 3-percent random sample of hospital discharges to include the application of the generic quality screens used by PROs in the review of other Medicare hospital cases, as well as discharge review using criteria developed by the QRO (also paralleling PRO review responsibilities);
- admissions within 30 days of discharge from an acute care hospital;[25]
- all transfers from a hospital with which the HMO or CMP does not have an agreement (regarding payment for members' care) to a hospital with which it does have an agreement (Reviews include admissions review, generic quality screens, and appropriateness of transfer.);
- samples of all patient care records for all non-trauma deaths. (The sample sizes depend on the level of review as follows: for limited review, 5 percent; basic review, 10 percent; intensified review, 100 percent.); and
- review of a subsample of cases from HMOs and CMPs in the limited review category (The size of the sample is determined by the number of beneficiaries enrolled, ranging from 20 in plans with less than 500 Medicare enrollees, to 200 in plans with 5,000 or more Medicare enrollees.).

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[25] Readmissions within 15 days of discharge from an acute care hospital in HMOs and CMPs, under limited review a 25 percent random sample must be reviewed; under basic review, a 50 percent random sample; intensified review, all such readmissions. (Readmissions within 7 days and 8-15 days are reported separately.) For readmissions within 16-30 days of discharge from an acute care hospital, under limited review, a 15 percent random sample is reviewed; basic review, a 25 percent random sample; intensified review, all such readmissions.

Figure 4.2: Thirteen Conditions Requiring HMO or CMP Review

Conditions	ICD-9-CM Codes	Time Period Minimums fc Record Review
*1. Diabetic Complications		1. 3 months prior. 3 months post
Diabetes with Ketacidosis	250.10 250.11	
Diabetes with Hyperosmolar coma	250.20 250.21	
Diabetes with other coma	250.30 250.31	
Hypoglycemic coma	251.0	
2. Acute appendicitis with gen. peritonitis	540.0	2. 1 month prior
Acute app. with peritoneal abscess	540.1	
3. Hypertensive Problems		3. 6 months prior
Intracerebral hemorrhage	431	
Other and unspec. intracranial hem.	432.0-432.9	
Occlus and stenosis of precereb art	433.0-433.9	
Occlusion of cerebral arteries	434.0-434.9	
Transient cerebral ischemia	435.0-435.9	
Ac, ill-defined, cerebrovas disease	436	
Other ill-defined cerebrovas disease	437.0-437.9	
4. GI Catastrophies		4. 6 months prior
Acute gastric ulcer with hemorrhage without obstruction	531.00	
Chronic or unspecified gastric ulcer with hemorr without obstruction	531.40	
Chronic duodenal ulcer with hemorrhage without obstruction	532.40	
Unspecified intestinal obstruction	560.9	
*5. Gangrene of the Extremity	785.4	5. 6 months prior. 6 months post
6. Operations for Breast Malignancy		6. 1 year prior
Other biopsy of breast	85.12	
Local excision of lesion of breast	85.21	
Resection of quadrant of breast	85.22	
Subtotal mastectomy	85.23	
Unilateral simple mastectomy	85.41	
Bil. simple mastectomy	85.42	
Unil. extended simple mastectomy	85.43	
Bil. extended simple mastectomy	85.44	
Unil. radical mastectomy	85.45	
7. Malignant neoplasm of GU organs		7. 1 year prior
Mal. neoplasm of uterus, part unspec.	179	
Mal neopl of corpus, except isthmus	182.0	
Mal neopl of isthmus	182.1	
Mal neopl of spec site of body ut	182.8	

Source: Health Care Financing Administration, 1987

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Figure 4.2: (Continued)

Conditions	ICD-9-CM Codes	Time Period Minimums for Record Review
*8. Adverse drug reactions		8. 3 months prior. 3 months post
Hemmorrhagic disorder due to circulating anticoagulants	286.5	
Paranoid &/or Halluc. statas induced by drugs	292.1	
Pathological drug intoxication	292.2	
Poisoning by primaril sys. agents	963.0-963.9	
Poisoning by anticoagulants	964.2	
Poison. by analgesics, antipyretics, and antirheumatics	965.0-965.9	
Poison. by unspec. sed or hypnotic	967.9	
Poison by parasympathomimetics	971.0	
Poisoning by agents prim. affecting cardiovascular system	972.0-972.9	
Poison by water, mineral and uric acid metabolism drugs	974.0-974.7	
Poison by unspec drug or medicine	977.9	
Unspecified adverse effect of drug, medicinal and biological substance	995.2	
*9. Other cellulitis and abscess	682.0-682.9	9. 3 months prior. 3 months post
10. Malignant neoplasm of colon	153.0-153.9	10. 1 year prior
*11. Hypokalemia	276.8	11. 3 months prior. 3 months post
*12. Septicemia	038.0-038.9	12. 3 months prior. 3 months post
*13. Pulmonary embolus	415.1	13. 3 months prior. 3 months post

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Intensified Review

The criteria for moving a plan from limited or basic to intensified review are specified by HCFA in the QRO scope of work. Generally, plans under limited or basic review are moved to intensified review if (1) quality problems are found in 5 percent of the randomly selected subsample for a 3-month period or cumulatively over the course of the contract (a minimum of six cases), or (2) 5 percent of cases (with a minimum of six cases) reviewed in the other review areas for a 3-month period or cumulatively over the course of the contract are found to have problems related to standards of quality, access, or appropriateness of care. According to the scope of work, HMOs and CMPs placed under intensified review will remain in this status for 6 months. Their status is then reviewed, and if QRO analysis indicates that the HMO or CMP no longer exceeds the threshold limits, the plan can revert to its previous review status (basic review or limited review plus the random subsample).

Additional QRO Responsibilities

Like PROs, QROs will be required to develop profiles to identify aberrant patterns or outcomes of care by physicians, hospitals, or other practitioners in HMOs or CMPs or across plans, but the types of profiles to be developed are not specified. The scope of work calls for quarterly profiling and for contractor interventions when the profiles reveal possible problems. QROs are also required to report any gross and flagrant violations to the appropriate HCFA officials, to initiate sanctions against providers as necessary, and to investigate complaints from Medicare beneficiaries enrolled in HMOs or CMPs. HCFA systems for reviewing the effectiveness and efficiency of QRO review methods are still under development.

Conclusions

Medical review in the Medicare program includes a wide array of quality assessment methods, ranging from automated screens to formal protocols for reviewing medical records. In addition to the carriers' and intermediaries' efforts to create effective screens and profiling systems, 54 PROs have devised systems for identifying and addressing particular types of quality of care problems, which are not coordinated with carrier and intermediary activities. Analogous methods for reviewing ambulatory care in Medicare HMOs and CMPs are currently being developed. HCFA itself is developing methods to help target possible quality of care problems.

In fiscal year 1988, about 400 million Medicare claims will receive some scrutiny by carriers, intermediaries, and PROs. Over one quarter of all Medicare admissions to acute care hospitals will be manually reviewed by PROs. The medical review systems in place, and particularly the PRO program, involve extensive, costly, and time-consuming examination of medical records by trained health professionals. There is, however, practically no information available to document how all these review efforts are working. In particular, it is not known whether PROs are effectively identifying and correcting quality of care problems and changing physician and hospital behavior in ways that raise overall levels of quality of care.

The wide variation in PRO quality objectives and review criteria and the systems PROs have developed for addressing suspected problems provide an opportunity to learn more about which methods are most effective. To do so, comparative analyses of the systems in place are essential. The need for such assessments is underscored by the wide divergence in the incidence of quality problems identified by PROs.

The PROMPTS-2 and SuperPRO systems for reviewing these quality assessment activities do little to generate information on how well these methods work. HCFA has not encouraged the SuperPRO to analyze the comparative effectiveness of individual PRO methods for identifying quality problems and has not designed data reporting systems that facilitate this type of analysis. (See chapter 5.) Both the SuperPRO and PROMPTS-2 reviews focus on whether, once a case is selected for review, it is reviewed correctly, rather than on whether potential quality problems are being selected for review. In part, this reflects the dual role of the PROs, who are responsible for both controlling unnecessary or inappropriate utilization of Medicare services and assessing quality of care. As the system is currently designed, the majority of cases selected for review are those targeted because of utilization concerns; for these cases, quality review is performed as a collateral activity. If PROs are to be effective in their role as quality of care reviewers, however, HCFA needs to know how to structure the selection and review of cases to maximize the efficiency of PRO quality reviews.

The advantages and disadvantages of methods to target quality reviews also need to be assessed. As is discussed in chapter 3, carriers and intermediaries use computer screens and profiling techniques to identify coverage and utilization problems, but not to target specific instances of substandard care. PROs build their own profiles from case review data. Intramurally, HCFA has devoted substantial resources to develop methods to identify aberrant patterns of patient mortality following hospitalization. Yet, despite these efforts, little is being done to systematically explore whether there are ways to integrate these varied approaches to better target cases with suspected quality problems.

The expansion of PRO review to Medicare HMOs and CMPs reinforces the need for systematic evaluation. Because these reviews may involve extensive examination of ambulatory care, the current PRO review methods cannot be simply transferred to review care provided in prepaid settings. These reviews are just beginning, and HCFA has the opportunity to assess how well the new ambulatory review systems actually work. An adequate evaluation plan must allow for comparisons among the systems, including comparisons of their ability to identify quality problems and to improve the processes and outcomes of patient care over time.

Recommendations

We recommend that the Secretary of HHS direct the Administrator of HCFA to fund additional studies to analyze the comparative effectiveness of particular PRO review methods, and the utility of current methods for establishing PRO quality objectives. These analyses should include assessments of whether different written review criteria or protocols generate significantly different rates of problems identified, and whether the identification of problems using these methods leads to significant changes in the incidence of quality problems over time.

We recommend that the Secretary of HHS direct the Administrator of HCFA to initiate studies to assess the strengths and weaknesses of the current assignment of responsibilities among carriers, intermediaries and PROs with respect to processing and screening Medicare claims data and performing medical reviews to identify quality of care problems and substandard providers and suppliers. These studies should specifically examine whether a realignment of responsibilities could improve the efficiency and effectiveness of Medicare quality review activities.

We recommend that the Secretary of HHS direct the Administrator of HCFA to develop comparative information on the effectiveness of the quality review methods used by the peer review organizations reviewing quality of care in Medicare HMOs and CMPs. These studies should also produce comparative information on the overall levels of quality of care provided in the participating HMOs and CMPs. This would require the collection of standard information on the use of services and health care outcomes across plans.

Chapter 5

Existing Data Resources for Assessing Quality of Care

As described earlier, Medicare review activities have not been designed to produce nationally generalizable information on the overall quality of care provided to beneficiaries. Nevertheless, some data collected in the course of routine program operations can be used as indicators of quality. These include basic billing data processed by Medicare contractors (carriers, intermediaries, and PROs), information gathered by the survey and certification process, and program data collated and analyzed by HCFA. The extent to which such data can be helpful for measuring and monitoring quality of care is examined below.

The usefulness of Medicare administrative data for measuring quality of care is determined by (1) the types of information about quality they can provide; (2) the accuracy and completeness of the data elements; and (3) the ways in which the data are reported, organized, and stored. The existing Medicare data system is large and complicated, reflecting the decentralized nature of claims processing and review. However, HCFA is now in the early stages of a major redesign of its data system. This presents an opportunity to significantly improve the program's ability to produce information on quality of care without major additional costs or organizational burdens.

Contractor-Generated Data on Quality of Care

The basic sources of patient-level information for monitoring Medicare services are billing data and Medicare enrollment and eligibility data that carriers and intermediaries can access from central HCFA files. Medicare billing data, however, have gaps that limit their utility for measuring the structure, process, and outcomes of care.

The Sources of the Data

Most of the information maintained by carriers and intermediaries is limited to what is submitted on claim forms and information received in response to queries to HCFA to check on beneficiary eligibility or deductible status. Only in the rare instances of full-scale reviews (described in chapter 3) do carriers obtain medical records and other supporting information. Intermediaries limit their data collection to information from claims and queries, except for medical reviews of skilled nursing facilities, hospices, and home health agency claims, which may require review of medical records.

The initial data source for PRO Medicare reviews is the Unibill file of Medicare bills generated by intermediaries. After verifying that interim bills have been excluded from the data files, and inaccurate and incomplete records have been corrected, PROs base their reviews on actual discharge bills for hospitals that are covered by the Medicare prospective payment system. PROs also review a sample of bills from PPS-exempt hospitals.

PROs may obtain other relevant data from intermediaries or other sources as needed, but they are prohibited from collecting or having others collect for them any information that duplicates that which HCFA requires intermediaries to collect. PROs may, for example, obtain data from HCFA or Social Security beneficiary files to verify posthospital mortality data.

Data Relevant to Quality of Care Assessment

Inpatient bills submitted to intermediaries contain some information on patient outcomes, primarily patient discharge status indicating, for example, whether the patient died in the hospital or was discharged to a subacute care facility (see appendix V), and date of death. Billing files accumulated over time also provide information about previous use of Medicare inpatient services, which allows the computation of eligibility, copayment, and deductible requirements over a Medicare benefit period. Thus, outcome measures for inpatient services that can be derived from billing data are mortality, and to a limited extent, morbidity (as indicated by readmissions and some inpatient diagnoses) and disability (as indicated by admission to rehabilitative subacute care). These measures are discussed in greater detail in chapter 6. Obtaining accurate data for these relatively crude outcome measures may require linking information from several sources.

Diagnostic information, which can indicate negative outcomes as well as provide the information required for many analyses of the process of care, is reported on part A billing forms. Although part B billing forms include space to indicate the patient diagnosis for which the services were given, HCFA does not require claims processors to enter the diagnostic information on manually submitted forms onto computerized billing files, and no diagnostic data are included in billing files submitted to HCFA by carriers.[1] The only relevant outcome information available on part B billing forms are procedure codes, some of which may indicate possible negative patient outcomes, such as procedures used in treating specific postoperative problems.[2]

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[1] This is apparently because for cases where patients submit bills directly to the carrier (that is, when physicians do not accept assignment), HCFA believes the diagnostic information may be unreliable. This issue is discussed below.

[2] For example, codes 52606 and 52650 are used to indicate procedures used to treat postoperative complications (bleeding and infection) of transurethral prostate surgery.

However, as we discuss in appendix III, HCFA does require that claims submitted directly from providers to carriers through the electronic media claims system include ICD-9-CM codes. Further, some carriers have already developed procedures for coding diagnostic information on manually submitted paper claims as part of their self-initiated utilization review systems. Some carriers using diagnostic data report that these screening activities are cost-effective. Diagnoses can, for example, be linked with procedures data to detect inappropriate use of diagnostic tests. Conversely, diagnoses without the appropriate tests could indicate inadequate care. Thus, there is the potential for expanding the collection of diagnostic data on part B bills and strengthening the availability of information to monitor both processes and outcomes of care.

There is more information available on process than outcome indicators of quality. Inpatient part A billing forms contain information on surgical procedures and services provided to the beneficiary; outpatient part B bills contain information on types of visits and procedures performed. This information is reported using standardized ICD-9-CM diagnosis and procedure codes for part A inpatient admissions and HCFA common procedures codes for part B services.

Bills contain very little information on the structural characteristics of Medicare providers. However, bills always contain provider numbers, which would allow billing information to be linked with provider information such as that contained in the provider of services file maintained by HCFA (see below). Statistical profiles of providers (such as utilization patterns and charges) can be linked to individual beneficiary records.

Accuracy and Completeness of the Data

Contractors use three methods to check the accuracy of data submitted to them: edits, screens, and reviews. Extensive data edits check primarily for completeness and consistency; they are discussed below. Data accuracy may also be checked as a byproduct of the various screening and review activities discussed in chapter 3.

Carriers and intermediaries apply consistency edits to ensure that all required fields on the Medicare billing forms contain numbers or letters in the appropriate ranges.[3] This step ensures that the required information is complete and appears to be appropriate. In addition, all part A bills are passed through the Medicare code editor to detect incorrect billing information which would affect an appropriate DRG assignment.[4]

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[3] A computer edit program looks for invalid data or inconsistencies in each bill. For example, a month greater than 12 or more than 60 lifetime reserve days used are invalid data items. However, consistency edits do not compare data on the bill with information in other HCFA records but only check for consistency of the data in each bill.

Carriers and intermediaries perform utilization edits after the consistency edits to determine patients' eligibility and any copayment obligations. At this point, information on the bill is compared to data on HCFA's health insurance master record, which contains up to five of the beneficiary's most recent benefit periods.[5] HCFA's reply to an intermediary's health insurance query or admission notice indicates the number of days of care remaining and deductibles to be met as of the last transaction. Only for a small fraction of the cases would the accuracy of the data be verified beyond these initial consistency and utilization edits.

For part A inpatient services, PROs have assumed the major responsibility for ensuring the accuracy of billing information. They perform some of the same edit functions described above. In addition, in the course of performing case reviews, PROs review medical records to verify the accuracy of DRG coding. Intermediaries may find data errors in other part A bills in the course of their medical review of skilled nursing facility, home health, or other part A bills. As noted above, few part B bills receive the scrutiny which would identify significant problems in the accuracy of data recorded on billing forms not identifiable through standard edits or screens.[6]

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[4] After the billing information passes the code editor program, it is sent through the DRG "grouper" program. This program uses all available diagnosis and procedure codes, age, gender, and discharge destination information to determine a major diagnostic category, a DRG number, and the procedure, diagnosis, and secondary diagnosis (if any) used in determining the DRG. Once the DRG has been determined by the "grouper," the "pricer" program determines the price upon which to base reimbursement to hospitals under prospective payment.

[5] Bills that failed one or more consistency checks are screened for only three items: (1) name and claim number, (2) eligibility for part A or part B benefits during the billing periods, and (3) matching for an "open" item (a prior admission notice, discharge bills, or deletion queries "close" the item). Records of bills passing the initial edits are used to update the beneficiary's health insurance master record, the provider master file, and are posted to a history record of completed billing transactions. In cases where an interim, final, or discharge bill is processed for inpatient services or home health visits, intermediaries also generate a notice of beneficiary utilization. Intermediaries process bills in order of the date in which services were provided within a benefit period. If a bill is not related to a preceding admission ("open" item), it will not be processed until a final bill for the open item is received. However, unprocessed items are kept and taken into account in determining the benefit period charges along with previously processed items.

[6] In fiscal year 1985, for example, one carrier selected 280 physicians and suppliers for review from a total of 9,338 who were paid $20,000 or more during fiscal year 1984. Of the 280 providers selected for review, the carrier reported 92 cases of preliminary screening; of those, 82 went to integrity review; and of those, 27 became full scale reviews. The previous fiscal year, 10 cases reached full-scale review.

Data Reporting

Most of the reports submitted by Medicare contractors document progress on processing claims and the status of activities related to the various review functions. The major types of reports that contain information relevant to identifying or correcting possible quality of care problems are described in table 5.1.

Table 5.1: Primary Quality of Care and Quality-Related Data From Carrier, Intermediary, and PRO Case Reviews

Type of Review	Type of Quality-Related Information
Carriers and intermediaries	
Utilization screens	Screens applied, added, and dropped; claims denied (totals for coverage, necessity, and appropriateness of sources of care)
Providers, suppliers and physician	Numbers under investigation, identity of physicians, suppliers under review, results of full-scale investigations
Sanction activities	Cases referred to Inspector General for possible sanction, sanctions effected
Peer review organizations	
Generic quality screens	For each screen and overall: review coordinator and physician advisor case finding totals for each type of case selected for review
Short-stay reviews	Admissions denied (including premature discharges), total quality problems identified, number failing generic quality screens
Quality interventions	Number of physicians and hospitals receiving written notification of quality problems, formal education, intensified review, impending sanction, or other action (repeat notification or new physician-hospital contact indicated)
Premature discharges	Number of denials for premature discharge for each type of case selected for review
Sanction activity	Substantial, gross and flagrant violations for physicians, hospitals: numbers under development, notices sent, decisions pending, referrals to Inspector General (by number of discharges involved); utilization, quality issues differentiated
Objectives for generic screen, admissions, and adverse outcomes	Description of objectives, performance measures, target, performance level, explanation if target not met
SuperPRO	
Generic quality screens	Screen failures, agreement or disagreement with PRO findings for a sample of each PRO's cases
Confirmed quality problems	Number of cases with any physician advisor-confirmed quality problems for a sample of each PRO's cases
PROMPTS-2	
Generic quality screens	Screen failures, agreement or disagreement on a sample of each PRO's cases

Claims Processor Reports

Most reports sent to HCFA deal with the number and dollar amounts of claims processed and the administrative costs of performing these functions. Intermediaries send HCFA the processed and adjusted billing information and summary reports on the number and dollar amounts of claims processed. In addition, intermediaries prepare for the responsible PRO a copy of Unibill claims for inpatient hospital stays, including specialty hospitals and swing-bed claims for skilled nursing facility level services.

Most of the information that carriers report to HCFA deals with the number of claims processed; the number and type of screens used, added, and dropped; numbers and amounts of claims denied or reduced; administrative costs; and net savings to the program. In addition, carriers submit quarterly reports of beneficiary overpayments, appeals, and physician and supplier overpayments. Data on suspected quality of care problems are not included in carrier or intermediary reporting systems. Further, aggregate data on denials do not permit identification of possible quality problems related to access to appropriate care. For example, under the home health benefit, technical denials include both those based on determinations that a patient requires more than "intermittent" care for a short period of time and those based on the determination that a patient was not "homebound."

Intermediary and carrier reports to the HCFA central office include the names and provider numbers of providers and suppliers placed on prepayment review and those referred to the regional office for sanctions or criminal investigation. Carriers also report to HCFA the number of integrity and full-scale reviews conducted, the number of potential fraud cases and sanctions referred to the Office of the Inspector General, number of sanctions pending, and number of sanctions effected.

Peer Review Organization Reports

The data that PROs report to HCFA reflect the various types of screens and quality-related reviews they perform. PROs record and report to HCFA the number of reviewed cases failing each of the generic screens by type or reason for review (for example, random sample, transfer) and the total number of cases reviewed by physician advisors that have verified quality of care problems. PROs also record any failures of PRO-developed quality screens or other PRO activities which uncover additional problems.

The summarized findings of PRO reviews are reported to HCFA on a monthly basis. They provide counts of specific screen failures for each type of reviewed case. Detailed reports show findings of review coordinators separately from those of physician reviewers, so it is possible to compare the results of initial reviewer screening with problems confirmed by physician reviewers. However, the information on the summary forms does not include any provider, patient, or physician identifiers, so it is not possible to determine the characteristics of potential problem cases on which initial reviewers and physicians tend to agree or disagree.

PROs also report to HCFA monthly the total number of premature discharges, by type of review. Separate totals are reported for the special subset of short-stay cases identified in the 3-percent random sample. PROs also report total numbers of admission denials in three categories: coverage (for example, where the admission is denied due to Medicare coverage requirements), utilization (for example, discharges, or proposed admissions for preadmission review, where the admission was found to be medically unnecessary or inappropriate), and denials of admissions made to circumvent prospective payments regulations.[7]

PROs also report monthly to HCFA the summary of all sanction activity. This report provides totals for sanction steps taken for substantial violations and gross and flagrant violations (see chapter 4); totals are reported separately for physicians and providers, and categorized by the nature of the problems; i.e. substandard care or unnecessary care.

Summary reports of PRO quality of care intervention activities, such as formal activities to educate providers or intensified review (see chapter 4), are made quarterly. As with findings from quality screens, no physician or hospital identifiers are included in these summary reports. Because the quality intervention plans are not standardized it is not clear whether reports can be used for purposes other than tracking individual PRO efforts over time.

Under the provisions of the current PRO contracts, PROs generate quarterly profiles of providers and physicians. Where aberrant patterns are identified but not yet explained or corrected, PROs are expected to perform the relevant profiling monthly. PROs do not have to generate hard copies of all profiles, but they must be able to produce profiles on demand by HCFA, and they must also produce a "Hospital Profile Summary Table" for each hospital at the end of each quarter. This table includes counts of discharges, deaths, average length of stay, transfers, average charges, and admission denials for each DRG for each hospital. The summary data are also transmitted to HCFA as an electronic data file. These data are the only provider-specific information routinely transmitted to HCFA by the PROs.

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[7] The PRO Manual transmittal no.5 states that these can be either premature discharges related to a subsequent readmission or transfer, or "other" admissions denials related to actions of hospitals in circumvention of prospective payment regulations; for example, readmissions for necessary care that could have been provided during a previous admission or inappropriate transfer to a unit exempt from prospective payment in the same hospital.

Superpro

For each review cycle, the SuperPRO reports its findings with regard to the generic quality screen it administers to all the cases it reviews from each PRO. However, these samples are designed to be representative of each PRO's workload, rather than comparable across PROs. Because PROs vary in the objectives that they have negotiated with HCFA and in the proportion of cases they review that involve standard, as opposed to negotiated, criteria, representative samples of cases from each PRO do not necessarily encompass equivalent sets of cases. One PRO's review cases may, for example, contain a disproportionately high percentage of cases falling into a particular DRG because of special review objectives formulated by that PRO. In making comparisons among PROs, it would therefore be useful to categorize cases according to their original basis for selection for initial PRO review; for example, random, readmission within 15 days, targeted DRG, and so forth. But while PROs report to HCFA separate figures for generic screen reviews of the 3-percent sample versus the 15-percent sample from PPS-exempt hospitals versus "all other" cases reviewed, the SuperPRO does not distinguish among the types of PRO cases sampled. It applies the same utilization, DRG coding, discharge, and quality reviews to every case it sees. As a result, the SuperPRO data system does not currently contain the information needed to construct categories of equivalent cases and to aggregate data nationally.

At the time we reviewed SuperPRO activities, neither the SuperPRO nor HCFA included the reason for case selection in their files of SuperPRO cases, and this information was not included in the SuperPRO's hard copy files for all PROs. Deriving nationally projectable rates of quality of care problems identified by the SuperPRO would therefore require going back to hard copy files or, in some cases, the individual PROs to determine why cases were selected for review.

PROMPTS-2 Reports

Like SuperPRO data, the program data generated by the PROMPTS-2 regional office reviews are designed to identify problems with individual PRO's performance, rather than to identify patterns or trends in quality of care problems. PROMPTS-2 samples are designed to be representative of each type of case reviewed by each PRO. The sample sizes are neither consistent across PROs nor proportional to the volume of cases PROs review. Without disaggregating cases selected as random review cases (which would not be of sufficient number in the smaller volume PROs to produce reliable estimates of quality problems) and adjusting for case volume, the re-reviews cannot be aggregated to provide national or regional estimates of "confirmed" quality problems.

Survey and Certification Data

Institutional providers of medical services participate in the Medicare and Medicaid programs through a formal certification process. Qualifications are reviewed at least yearly thereafter by state surveyors under agreements with HCFA to determine whether the facility should be recertified or terminated from participation in the Medicare or Medicaid programs. Information on the basic structural characteristics of certified facilities—size, staffing, staff qualifications, services provided, compliance with safety codes—is recorded on the standardized forms submitted to HCFA. Significant variations have been found, however, in the ways in which surveyors interpret the guidelines and criteria for identifying and reporting deficiencies in facility conditions or operations.[5]

As noted in chapter 2, HCFA has begun to redesign the survey and certification process, particularly as it pertains to long-term care facilities. These efforts include both greater standardization of processes and instruments and an increased emphasis on the collection of data directly related to patient care and well-being. The long-term care survey includes a patient interview component and new sampling methods for patient surveys. The system initially requires sampling 25 percent of the residents from each facility for indepth review. Those residents will be sampled randomly, but surveyors may also select additional residents for indepth review, based on their assessment of possible problems that require additional attention. Thus, the reviewed cases include both random and targeted cases. A more complex system providing for selection of cases stratified by facility size is planned. This should enable the generation of more precise national estimates of the status of nursing home residents, provided the total population and mix of randomly selected versus targeted cases within each facility is recorded.

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[5] See, for example, the Report of the Committee on Nursing Home Regulation, Institute of Medicine, Improving the Quality of Care in Nursing Homes (Washington, D.C.: National Academy Press, 1986), pp. 108ff.

A standard worksheet is used in each indepth review of residents' care to record the information obtained by observation, interview, and record review. The worksheet documents residents' ability to perform the basic activities of daily living, skin condition, a range of physical care and therapy needs, dietary needs, mental and emotional condition, and ability to function socially. Most items listed on the form represent patient care problems (for example, presence of rashes, problems with decubitus ulcers or catheters, weight problems, dehydration, privacy not maintained, signs of mental or physical abuse). In addition to interviewing and observing patients, surveyors review residents' medical records, care plans, and evaluations. These detailed worksheets are maintained by the states. While information from the patient surveys is used to support findings of various deficiencies that are reported to HCFA, the only data relating to the patient surveys that are recorded on HCFA automated files are data on average facility-wide skilled nursing patients' disability levels, as measured by patients' ability to perform basic activities of daily living.

HCFA has requested $3.5 million in fiscal year 1988 to enhance the data base on the health care and health status of nursing home residents. After the current planning stages, HCFA envisions a 5-year implementation period, including projects to identify and describe existing data resources, design a national data collection system, conduct pilot tests, train interviewers, and evaluate various program components.

HCFA has also made changes in the survey and certification process for home health agencies. Inspections now include visits to patients, although these are not yet mandatory for all facilities.[9] Surveyors determine whether visits are desirable or necessary based on their onsite facility review. The criteria for patient selection in the home health survey guidelines are less systematic than those for nursing home review (a minimum of three home visits per agency, but recommended sample of 10-20). Observations and information obtained by interviewing patients are incorporated into survey forms and specific citations of deficiencies are noted, but surveyors do not use standard patient interview worksheets, and no patient-level information is maintained.

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[9] The Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203) revised the survey and certification requirements for home health agencies. The law contains a requirement that standard facility surveys include visits to patients' homes, using a protocol to be developed, tested, and validated no later than January 1, 1989.

Central HCFA Data Systems

Information from Medicare claims and survey and certification activities feed into the central Medicare statistical system designed to provide data for evaluating and analyzing the administration of the Medicare program overall.[10] Table 5.2 summarizes the files containing information most likely to be useful for quality of care analyses.

Table 5.2: HCFA Data Files Most Useful for Quality Analysis

File name	Medicare services	Years	Size of sample	Key data
Hospital stay record file	Inpatient hospital	1983-1986	100%	DRGs, multiple diagnoses and procedures (ICD-9-CM); patient age, sex, dates of admission and discharge
Medicare provider and review file (MEDPAR)	Inpatient hospital	1982-1983 1984-1987	20% 100%	DRGs, one diagnosis (ICD-9-CM) and one procedure, discharge destination
Medicare history sample file	All	1974-1985	5%	Patient age, sex, race, date of death, diagnoses and procedures for hospital stays, charges for all services
Part B Medicare annual data file (B-MAD)	Inpatient and ambulatory physician care, diagnostic testing, durable medical equipment	1984-1985	5% (plus all end-stage renal disease)	Type of service, procedures, dates of services, type of provider, charges
Medicare automated data retrieval system (MADRS)	All	Current and prior 3 years	100%	Types of service, dates, charges, diagnoses
Provider of service file (POS)	Data on providers	1982-present	100%	Facility type, type of control, number of beds, services offered; number of RNs, LPNs, social workers

The hospital stay record file (and the medical provider and review file derived from it) contain extensive information on inpatient hospital stays, including diagnoses, surgical procedures, length of stay, and patient discharge destination. The recently developed Part B beneficiary medicare annual data (B-MAD) files include extensive patient-level information on the use of physician and other part B services for a 5-percent sample of beneficiaries. The Medicare history sample file includes longitudinal data for all covered services for a sample of Medicare beneficiaries. A new file still under development, the Medicare automated data retrieval system (MADRS) will include information on individuals' use and charges for the full range of Medicare services and charges, as well as inpatient diagnoses, in a format specifically designed to be useful to researchers. The provider of service file includes facility-level data that can be matched, by provider number, with the other files. Descriptions of the data in these files are presented in appendix V.

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[10] There are three basic components of the Medicare statistical system: beneficiary enrollment and eligibility data, hospital insurance (part A) and supplementary medical insurance (part B) data, and provider of services data. HCFA, Program Statistics, Medicare and Medicaid Data Book, 1984 (Washington, D.C.: U.S. Government Printing Office, June 1986), p. 54.

Accuracy and Completeness of Data

The Medicare statistical system relies heavily on the activities of claims processors for ensuring the accuracy and completeness of data. As the previous discussion has demonstrated, the verification of billing data consists mostly of internal consistency and logic checks. Independent confirmation of the accuracy of particular data elements, based on reviews of medical records, focuses primarily on payment-related questions, for example, were diagnoses and procedures recorded correctly, so that the appropriate DRG assignment could be made?

Medicare editing systems virtually ensure that submitted bills are complete, or at least contain all the information necessary for processing claims. Little is known about the volume of bills that are never submitted.[11]

Information on the overall accuracy of the data in the Medicare data system is very limited. The last major study of the quality and accuracy of Medicare hospital data was conducted by the Institute of Medicine in 1977 (using 1974 data). This study focused on six data elements (date of admission, date of discharge, sex, primary diagnosis, presence of additional diagnoses, and primary procedure). The accuracy of admission and discharge dates was found to be extremely good. For diagnosis and procedure data, however, which are key to monitoring quality of care, there were problems in coding.[12]

Some improvement in coding accuracy may have occurred with the introduction of the ICD-9-CM system. The emphasis on diagnosis and procedure coding in the DRG system is also believed to have led to greater accuracy in coding. PROs specifically examine the accuracy of diagnostic coding as part of their DRG validation function. The increasing sophistication of carrier edits and screens is also designed to improve accuracy of coding for procedures, although information on the accuracy of coding on part B records is very limited.[13] Nevertheless, there has been no systematic, national assessment of the accuracy of the key data elements in HCFA files since 1977, so the extent to which data problems undermine quality assurance activities is unknown.

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[11] A report prepared under contract to HCFA reviewing Medicare data from Florida and South Carolina found, for example, that "in a substantial number of cases some expected claims appear to be missing." In some cases, there were no part B bills for patients either preceding hospital admission or after discharge. This could reflect problems in the submission of claims or problems related to continuity of care. In addition, however, there were instances where there were no physician bills associated with inpatient stays. A more precise estimate of missing bills was not developed as part of the study, but the potential problem was raised as an issue that should be pursued. Mandex, Inc., "Developing MD-DRG Algorithms," (Vienna, Va.: February 6, 1985).

[12] Overall, the study abstractors agreed with the determination of principal diagnosis found in the HCFA data about 60 percent of the time. But the levels of agreement varied considerably by diagnosis. For patients with chronic ischemic heart disease, the level of agreement was about 37 percent; for diabetes mellitus, about 50 percent. Institute of Medicine. Reliability of Medicare Hospital Discharge Records (Washington, D.C.: National Academy of Sciences, November 1977).

The accuracy of data elements that do not directly affect reimbursement amounts is especially problematic. Because DRGs often encompass broad ranges of ICD-9-CM codes, some coding errors do not affect DRG assignment, but may be important in quality and utilization review. The coding of complications and/or secondary diagnoses has been immaterial for assignment of many DRGs, particularly for patients who are over 69 years old, because age currently serves as a proxy for complicating conditions in many DRG assignments.[14] Neither PROs nor intermediaries have strong incentives to verify information on hospital discharge abstracts detailing type of admission (billing form categories are emergency, urgent, or elective newborn, and unknown) or source of admission (billing form categories are physician referral, clinical referral, HMO referral, transfer from a hospital, transfer from a skilled nursing facility, or transfer from another health care facility), because this information is usually not used for determining eligibility for services, coverage of services, or payment amounts. This type of information could, however, be useful in screening for possible quality of care problems. (See chapter 6.)

Serious questions about the accuracy of discharge destination data recorded on inpatient hospital and skilled nursing facility bills have also been raised. This data element indicates whether a patient has been discharged, and if so, where to (home to self care, to a short-term hospital, a skilled nursing facility, an intermediate care nursing facility, to some other type of health care facility, to home with home health care services, discharged against medical advice, or died in the hospital). Data problems include coding errors and missing data.[15]

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[13] A recently completed study which compared 1981 part B Medicare claims data to information abstracted from medical records found that for three specific procedures studied, the claims file data was accurate in over 96 percent of the 4,988 cases reviewed. J. Kosecoff, et al., "Obtaining Clinical Data on the Appropriateness of Medical Care in Community Practice," Journal of the American Medical Association (November 13, 1987), p. 2541.

[14] The Prospective Payment Assessment Commission has recommended that DRGs not be defined based on age, and the Secretary of HHS has concurred with this recommendation and proposed to eliminate age over 69 as a criterion for DRG classification. Prospective Payment Assessment Commission, 1988 Adjustments to the Medicare Prospective Payment System Report to the Congress, November 1987, p. 28.

A study of Medicare discharges in California found that 23 percent of patient deaths within 20 days of discharge (as recorded on state vital statistics records) had been incorrectly coded on hospital discharge abstracts. Of these, a large proportion were reported as discharged alive when they had in fact died in the hospital. These problems have been confirmed by others.[16] HCFA's Bureau of Program Operations has initiated a study of the accuracy of mortality data, but results are not yet available.

Errors in the coding of inpatient deaths may have important implications both for the accuracy of some DRG coding and for the validity of PRO hospital and provider profiling efforts. Erroneous coding of discharge disposition can lead to incorrect DRG assignment. In cases of myocardial infarction, for example, patients discharged alive are assigned to DRG 121 or 122, which are reimbursed at a higher rate than the DRG for myocardial infarctions resulting in inpatient death (DRG 123). More important, erroneous coding may undermine the validity of the profiling activities that PROs use to help target their review activities. If the misreporting of inpatient mortality is random, it would not seriously affect the validity of analyses designed to identify outliers. But if particular hospitals seriously and routinely underreport inpatient mortality, they might not be identified as outliers when they should be so identified. Conversely, hospitals that report mortality data accurately could appear to have relatively high rates.

To some extent, the inclusion of date of death from Social Security Administration files on inpatient billing records could mitigate this problem. However, research in progress has suggested that this information is also problematic.

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[15] GAO, Information Requirements for Evaluating the Impact of the Medicare Prospective Payment System on Long-term Care Services, GAO/PEMD-86-8 (Washington, D.C.: February 21, 1986), p. 6; HHS, Report to Congress: The Impact Of the Medicare Hospital Prospective Payment System, 1984 Annual Report (Washington, D.C.: November 1986), pp. 8-15.

[16] California Medical Review, Inc. Final Report, Premature Discharge Study, December 10, 1986. HCFA contract no. HCFA-500-87-0536-0032; M.S. Blumberg, "Comments on HCFA Hospital Death Rate Statistical Outliers," Health Services Research 21(6), pp. 716-8.

Organization of the Data

Many analyses of quality of care require linking Medicare claims data over time and across covered services. For example, some quality review methods link diagnostic or procedure data from physician visits with inpatient information to detect possible surgical complications. The absence of linked data precludes this possibility. PROs' review of the appropriateness of hospital readmissions could be strengthened if they had access to information on the use of posthospital and ambulatory services. Currently, beneficiary and provider identification numbers can be used to link data from different Medicare files, but the size and structure of the files makes this very difficult. Manipulating both part A and part B files to obtain a full picture of patients' use of various services over time and comparing patterns of service use to care outcomes has been particularly problematic. The creation of the MADRS file represents one effort to provide this type of information for research and policy analysis.[17]

HCFA is currently developing two major and closely related projects that will restructure the entire Medicare administrative data system. The first, the combined A/B working file project, is already well underway. It is designed to create an online beneficiary data file that contains all entitlement and utilization information in one file. This will allow contractors to have immediate access to information they need to process bills and will expand the possibilities for establishing prepayment screens. The system is also intended to provide a mechanism for future system enhancements, including the integration of PROs into HCFA's evolving on-line data system.

The second, even more ambitious undertaking is HCFA's Project to Redesign Information Systems Management (PRISM). This will include the design and installation of an entirely redesigned, integrated online Medicare and Medicaid administrative data system accessible to carriers, intermediaries, and PROs, as well as to HCFA managers and analysts.

A $9.28 million appropriation was requested for this project for fiscal year 1988. The analysis and system design phase of the project is now underway; the project is currently scheduled for completion in 1990. The statement of work calls for an interactive system including data required for the processing of queries regarding enrollment, eligibility, and so forth, plus a limited volume of part A bills, and a limited volume of part B bills. The statistical and decision support systems are to be designed so that users have access to both online and historical files.

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[17] HCFA plans to make the MADRS file available to PROs in the next contract cycle. The Pennsylvania PRO is currently using MADRS to identify skilled nursing facility, home health, and hospital outpatient care for reviews of selected readmissions cases. (See appendix VII.)

Conclusions and Recommendations

The data files maintained at HCFA contain information that could be used to measure quality of care. It is possible to link provider-level and patient-level files to create data bases to examine patterns of service across providers, regions, types of service, and so forth. There are basic problems, however, with the completeness of the information reported to HCFA, with systems for verifying the accuracy of these data, and with the way the data are reported and maintained. Basic information on diagnoses is not included in HCFA part B claims data. Information that is needed to analyze patient care outcomes, including inpatient mortality and discharge destination, is rarely verified. The information obtained from quality monitoring activities is usually not reported to HCFA in a form that could be used to develop national estimates of the incidence or distribution of quality of care problems. If these problems were corrected, Medicare's capacity to measure and monitor quality of care would be improved.

We believe that adding diagnostic information to part B physician claims data would increase the usefulness of these files for monitoring care, both in ambulatory settings and over episodes of illness.[16] Diagnostic information could be used to identify post-surgical complications and aberrant patterns of posthospital care associated with particular illnesses, as well as possible instances of inappropriate services before hospitalization. Adding diagnostic information would not require changing current bill forms, nor would computer layouts for reporting part B data need to be revised. This information is already required for part B claims submitted electronically. The diagnostic coding system currently in use for inpatient services, ICD-9-CM, is already being used by carriers in their medical review of physician claims. The primary expense would be costs of training additional people to use the coding system and keying in the data. As we note in appendix IV, implementing this recommendation would involve no costs at all for some carriers. For others, the training and computer costs would be considerable. Savings derived from the improved efficiency of prepayment and postpayment screens might offset the costs of implementing this recommendation, especially over the longer term.

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[16] This position has also been taken by the National Committee on Vital and Health Statistics in a report on Statistical Aspects of Physician Payment Systems, issued in July 1986.

The introduction of systems for routinely coding and reporting part B diagnostic information could be coordinated with planned changes in contractor data reporting associated with the new PRISM system. Training costs might be reduced by implementing both simultaneously. Physicians would have to supply diagnostic information on ambulatory claims, whether they accept assignment or not. Further, accuracy would have to be monitored through profiling and routine checks performed in the course of claims review (see below).

Requiring that physicians submit diagnostic information on claims or take responsibility for providing this information to patients would require changing current regulations governing the submission of part B claims, and could require new legislation.

Recommendation

We recommend that the Secretary of HHS direct the Administrator of HCFA to require that physicians include written descriptions and ICD-9-CM diagnosis codes on part B claims, that this information be included in the carrier claims processing system, and that it be included in the B-MAD files and MADRS files.

A moderate level of error in Medicare data elements, particularly if randomly distributed, might not greatly impede analyses of quality of care. Of greater concern is the potential for systematic error in data elements such as diagnostic and procedure coding or mortality data (for example, systematic underreporting of in-hospital deaths). Errors in coding discharge destination and type or source of admission, information that could be useful in characterizing patients' condition at admission or discharge, also limit the usefulness and integrity of quality assessment efforts based on administrative data.

The current review systems involve extensive examination of both billing and medical record information; the resources required to document data errors uncovered in the course of claims processing and medical review would involve only marginal cost increases. Knowing the type and extent of such errors would be an important first step toward developing data quality standards that could be required of practitioners, providers, or suppliers submitting Medicare claims. HCFA could then monitor problems with these data (in the same way it currently monitors errors in data used to determine payment) and require some minimum level of compliance with reporting standards.

Recommendation

We recommend that the Secretary of HHS direct the Administrator of HCFA to require PROs, intermediaries, and carriers to routinely document and report incidents in which key data elements required for monitoring the quality of care are inaccurate. In particular, errors in mortality (date of death) and discharge destination, as well as all diagnostic and procedure data (not limited to DRG assignment) should be monitored. Tracking errors in the source and type of admission data fields should also be considered.[19]

Neither the existing central HCFA data systems nor the information generated by the medical peer review systems currently provide nationally representative or generalizable information on quality of care problems in the United States.

As discussed in chapter 4, the SuperPRO evaluation of PROs has been designed to validate each PRO's utilization and quality of care determinations. The SuperPRO re-reviews a representative sample of each PRO's cases, applying the HCFA generic quality screens as well as the criteria developed by each PRO. But each PRO selects cases based on its own quality objectives, a random sample of cases, and other cases where HCFA requires review. Because the reasons for including a case in the review have not been recorded by the SuperPRO and the data for each PRO are not comparable, the cases cannot be aggregated into a national sample. Identifying the randomly selected cases in the SuperPRO sample would allow analysts to create, using appropriate sampling weights, a nationally representative sample of PRO cases. This would, in turn, allow for the generation of nationally representative information on the types and distribution of quality problems identified by the generic screens. It would also allow for the creation of comparable national data for each SuperPRO review cycle, and thus allow estimates of changes in quality problems over time.

Information on the reason that a case was selected for review is readily available and could be added to SuperPRO files easily and cheaply. PROs use this information when reporting their review findings to HCFA, and many PROs currently include it in the abstracts attached to each case sent to the SuperPRO for review.

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[19] As part of a related evaluation, we are currently examining the need for a nationally representative study of medical records to determine the nature and extent of missing and inaccurate data in the Medicare statistical system. Such a study would provide a systematic, definitive assessment of current levels of data accuracy. What is contemplated here is simply tracking blatant data errors and holding providers accountable for improvement.

Recommendation

We recommend that the Secretary of HHS direct the Administrator of HCFA to modify the scope of work of the SuperPRO contract to provide that the case selection methods ensure that those cases selected for random review by each PRO are identifiable and that a nationally representative sample of cases can be constructed from the SuperPRO files for each review cycle.

To address the problem of developing generalizable information about quality of care in nonhospital settings, HCFA has requested $3.5 million for a project to design a mechanism for aggregating state-level information collected through its new long-term care survey and certification program. Such an ongoing data base would allow analysts to examine patient care needs, facility conditions, and changes in quality of care over time.

Recommendation

We recommend that the Secretary of HHS direct the Administrator of HCFA to assign a high priority to completing the development of a central long-term care data system, including nationally representative data on the health care status, care needs, and health care outcomes of nursing home residents. We further recommend that these efforts be coordinated with developing a similar data resource, drawing on survey and certification data for other subacute care facilities, especially home health agencies.

Chapter 6

Long-Term Methodological and Data Resource Issues in Medicare Quality Assurance

In this chapter, we extend the discussion of strategies for assessing Medicare quality of care to consider the longer term research and developmental issues specified in the request letter. Chapters 3 through 5 focused on existing HCFA quality assessment activities and data resources and presented recommendations for short-term improvements. The discussion here turns to broader questions of research requirements to meet future needs for quality assurance. Below, we examine some underlying methods and measurement issues and how they are being addressed in ongoing HHS research. In chapter 7, we examine organizational and funding issues.

Methods and Measurement Issues

As noted in chapter 1, there are a variety of approaches to defining and measuring quality of care, each with strengths and weaknesses. No single approach will provide an assessment of all the technical and interpersonal aspects of medical care that affect its overall quality. The way that the Medicare program pays for health care, however, makes three issues particularly important: (1) selecting outcome measures that can effectively identify potential quality problems at the level of providers, institutions, or populations; (2) ensuring that fair and consistent criteria are applied in medical case reviews of the process of care; and (3) developing longitudinal data resources for examining the extent and distribution of quality of care problems. Our review of ongoing research to address these issues indicates that substantial progress has been made, both within HCFA and by others throughout the health services research community. Nevertheless, more needs to be done.

Outcome Measures

The development of useful outcome measures has become an important focus of quality assessment research. Indicators of prior problems in quality of care that affect patient outcomes, measured by death, disability, pain and suffering, or failure to achieve expected improvements in health status and functioning are essential for comprehensive quality assurance. HCFA is supporting a series of important studies designed to produce information on several outcome measures (mainly inpatient and posthospital mortality rates). Many of these studies are described in appendix VI. For example, one HCFA-sponsored study is examining whether outcome measures generated from administrative data (nonintrusive measures) are effective in identifying problems in quality of care that can be verified by extensive medical record reviews. However, several issues require additional attention.

Valid outcome measures are far easier to construct for discrete health care interventions, such as surgical procedures, than for lengthy or complicated courses of medical treatment. Much of the outcomes research, therefore, focuses fairly narrowly on inpatient care, and frequently on surgical care.[1] Methods for monitoring outcomes in ambulatory care are more problematic, because the health problems for which people seek ambulatory care are often nonspecific, reflecting signs and symptoms rather than precisely defined diagnoses, or may be chronic rather than acute. Consequently, definitive outcomes of ambulatory medical interventions are difficult to specify and to track. The need for indicators to address a wider range of health care outcomes is reflected in HCFA's solicitation for research proposals for fiscal year 1988, which specifically identifies research on outcomes of care for nursing homes, home health agencies and physician services as a priority.

Outcome measures involve tradeoffs between specificity and generalizability. A "generic" approach like that being used by PROs to identify nosocomial infections, premature discharges, unscheduled returns to the operating room, and so forth, may be insufficiently sensitive to variations in patients' symptoms or health problems. This could lead to flagging too many cases for review. Approaches which focus on a set of "tracers"; that is, specific conditions for which specific outcomes can be identified, may lose in generalizability what they gain in accuracy. It is not clear whether disease or condition-specific criteria that can target certain types of problems accurately can also provide an adequate view of the quality of care provided to a patient population as a whole. That is, the research has not yet established how many, or which sets of, specific outcome measures are needed to assure that significant quality of care problems are not overlooked.

The use of "general" outcome measures such as mortality and readmission rates raises some basic conceptual and methodological problems, the most significant of which is the need to adjust for variations in patient severity of illness. Without a good method for adjusting for severity, aggregate data on outcome measures have little meaning. For example, hospitals treating more severely ill patients should have higher-than-average mortality rates; comparing hospital mortality rates without knowing the patient populations' health status at admission is not likely to produce useful information.

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[1] As noted in chapter 2, the Joint Commission on the Accreditation of Healthcare Organizations is addressing this issue in a large-scale project to develop a set of outcome indicators for hospitals to use in their quality assurance programs. Part of that initiative includes the identification of a set of specific clinical "tracers" that can provide an accurate overview of quality of care in hospitals.

HHS is currently supporting several research projects to develop severity adjustors. Intramurally, studies conducted by the Health Standards and Quality Bureau and the Office of Research and Demonstrations examined several approaches to recombining diagnostic and demographic data available on billing forms to adjust for the case complexity and likely risk of negative outcomes for both inpatient and posthospital mortality. Extramurally, HCFA also funds researchers to develop other statistical approaches for adjusting for variations in the severity of conditions reported in claims data. (See appendix VI.)

The nature of HCFA's administrative data system, however, limits the development of outcomes measurement. Currently collected patient data that could be used to construct indicators of severity are limited to age, sex, readmissions, transfers, and discharge status, and diagnosis and procedures data (which can in turn be used to develop hospital case-mix measures) used in DRG assignment. As we discussed in chapter 5, the creation of a data system that permits examining current and past episodes of care based on both part A and part B services (particularly with the addition of part B diagnostic information) would expand the information available for developing severity-adjusted outcome measures.

If statistical adjustments using data from administrative files prove inadequate, it may be necessary to augment the information recorded on Medicare bills. One study funded by HCFA is examining the feasibility of abstracting clinical information from patient records and incorporating that information, and a measure of severity based on it, into Medicare hospital data. In that study, eight PROs are pilot-testing an approach, using a commercially-developed abstracting instrument that produces a severity score. The PROs will then examine whether this information can identify unusual patterns of outcomes; for example, higher-than-expected hospital inpatient mortality or length of stay among cases where severity of illness was relatively low. HCFA has also funded studies to examine the relative strengths and weaknesses (including the validity of specific clinical criteria) of alternative systems to assess severity of illness using physiological data. (See appendix VI.)

However, obtaining medical record information to calculate reliable severity scores for inpatient hospital stays requires additional resources and may not be immediately feasible for the full range of diagnoses and patient conditions. Further, even if cost-effective and reliable methods for obtaining severity information are identified, other potentially serious problems remain.

First, some of the severity measures being investigated by HCFA are proprietary. Problems could arise if the specific criteria used to create indexes or scores are unknown to users or not subject to adjustment or manipulation by them. For example, it could be difficult to establish precisely what is being measured, or whether one could discriminate among cases more effectively, if specific measurement criteria were altered, added, or eliminated. As discussed in chapter 4, establishing the validity, reliability, and effectiveness of the screening tools used by Medicare peer reviewers is an important HCFA program responsibility. These efforts could be hampered by having to rely on private organizations to validate and recalibrate their proprietary measurement tools. In addition, the "black box" nature of proprietary systems could lessen their credibility with the medical community. Hospitals or physicians might be selected as "aberrant" and subject to peer review scrutiny on the basis of what appears to be an arbitrary score, without HCFA (or the peer reviewers) being able to fully explain why a particular case or set of cases were assigned to a particular severity category. Thus, physicians or facilities might be asked to explain the appropriateness of their medical decisions without a thorough understanding of the logic by which their medical judgment was questioned.

Second, there may be legitimate disagreement about what medical or clinical information should be used in severity measures. The research undertaken at HCFA to date has included efforts to examine statistically the relative reliability and effectiveness of the criteria used in various severity measurement systems. A consensus among medical professionals is also needed to ensure that the measures used in quality review are appropriate.

Selecting Medical Case Review Criteria

To confirm the nature and extent of possible quality of care problems through screens and profiles, peer review of the actual process, as well as outcomes, of medical care is required. Methods for reviewing the process of care have been designed, but their validity is widely debated. Among the most difficult problems is balancing the strengths and weaknesses of explicit case review criteria that are detailed in written protocols and implicit criteria that set out general guidelines but demand a more extensive application of reviewers' medical knowledge and judgment.[2]

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[2] Implicit and explicit criteria are discussed in detail in A. Donabedian, Explorations in Quality Assessment and Monitoring, vol. 2, The Criteria and Standards of Quality (Ann Arbor, Mich: Health Administration Press, 1982), and vol.3, The Methods and Findings of Quality Assessment and Monitoring: An Illustrated Analysis (1985).

Implicit criteria provide greater flexibility and allow reviewers to adapt their assessments to specific features of individual cases. The application of medical judgment by professionals, however, may be time-consuming and expensive. An additional disadvantage is that the results are valid and reliable only if the reviewers are both expert and consistent in their application of medical judgment. Explicit review protocols may entail relatively high developmental costs, but once proven valid and reliable, they can be administered far more quickly and economically, usually by nonphysicians. A basic problem with explicit criteria is their relative inflexibility. This can lead either to lack of specificity, making the findings equivocal, or to the inclusion of too many or redundant criteria, creating incentives to provide unnecessary or inappropriate care.

The spectrum from implicit to explicit criteria can be illustrated with existing review approaches. At one end of a continuum is work being done by the Rand Corporation. This approach is designed to generate highly detailed explicit criteria to be used in assessing the treatment of specific medical conditions. Research activities include the development of lengthy standardized medical records abstracting forms that organize the information required to assess the appropriateness of medical decisionmaking for each condition under study.[3] Similarly, the Clinical Efficacy Assessment Project of the American College of Physicians has developed explicit guidelines for the appropriate care of patients with selected conditions, including cholecystitis and diabetes.

Other approaches also focus on specific types of care or care settings, but have somewhat less detailed explicit criteria. For example, the National Medicare Competition Evaluation (see appendix VI) used a panel of physicians to help select 51 explicit criteria for reviewing "basic care" in ambulatory settings and between 14 and 86 criteria for reviewing four medical conditions (diabetes, hypertension, colo-rectal cancer, and congestive heart failure).

Some review approaches include more generic sets of explicit criteria, often automated, that lead reviewers to apply additional, more implicit criteria for evaluating particular contingencies. A project funded by the HHS Office of the Inspector General used a standardized utilization review instrument, the appropriateness evaluation protocol, to help organize medical record data. Experienced nurse and physician reviewers then applied their own judgment in answering two "yes" or "no" questions for each case: (1) whether the care provided was "in accordance with professionally recognized standards of care," and (2) whether the patient was discharged prematurely.

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[3] A discussion of the Rand methodology is presented in M. R. Chassin, et al., "Does Inappropriate Use Explain Geographic Variations in the Use of Health Care Services?" Journal of the American Medical Association (November 13, 1987) pp. 2533-37.

Entirely implicit criteria have been used in studies designed to examine a wide array of cases. One, for example, allowed physician reviewers to use their clinical judgment and experience to evaluate hospital care. The physicians were provided copies of hospital medical records for a random sample of union members and their families and asked to evaluate whether the care provided in each case was excellent, good, fair, or poor. Ratings were compared across hospital services, for physicians with various levels of specialty training, for hospitals with and without medical school affiliations, and the like. Comparative analyses found differences in the ratings on the quality of medical care ratings among facilities and physicians.[4]

Evaluating the relative effectiveness of these various approaches to process review is a prerequisite of establishing how explicit and implicit criteria should be used in Medicare case reviews. Each PRO is required to adopt written utilization and quality criteria to be used by physician advisors in reviewing cases referred to them by the initial reviewers. HCFA is responsible for determining that PRO review procedures conform to the specifications set out in the contractors' scope of work, and utilization criteria are examined closely by the SuperPRO and HCFA. The selection and refining of quality review criteria, however, is considered to be a professional medical responsibility left to the individual PRO. This ensures that local medical standards and practice can be incorporated into peer review, as Medicare law and regulations require.

Despite the need to accommodate local standards when appropriate, case review by physician advisors is a component of a highly structured national review system. The determinations of physician advisors are the last step in a complicated process for assessing whether Medicare services are appropriate, necessary, and of acceptable quality, and in consequence, whether Medicare will pay for them. This makes the consistency and fairness of the system fundamentally important. While establishing explicit criteria for use by PROs is not a function assigned to HCFA, protecting beneficiaries (and the program itself) by ensuring that peer reviewers use those criteria, protocols, or review methodologies that most reliably and efficiently identify substandard care is a program responsibility. HCFA does not generally catalog the quality review criteria used by individual PROs, nor compare specific criteria or standards across protocols. Further, there is no system in place, in HCFA or the research community at large, for generating, assessing, validating, or updating either utilization or quality review criteria.

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[4] This study is discussed in A. Donabedian, Quality Assessment, vol. 3, pp. 186-93.

Longitudinal Research Data Bases

Currently, there are basic limitations in the information that can be gleaned from Medicare administrative data about the quality of care received by beneficiaries. Medicare pays for only about half of the elderly's medical care.[5] Thus, even complete and accurate records of Medicare-covered services cannot provide a full picture of beneficiaries' health care experiences or problems. Some services, such as most long-term care, and many routine medical costs, such as physical exams, drugs, eyeglasses and hearing aids, are not covered at all. Furthermore, existing national population surveys such as those conducted by the National Center for Health Statistics, or national medical expenditure surveys conducted by the National Center for Health Services Research and Health Care Technology Assessment typically do not include data from medical records, and may not include sufficient numbers of Medicare beneficiaries to allow analysts to determine the extent or distribution of problems of quality or lack of access to the full range of health services over time.

Longitudinal epidemiological data on patients with chronic diseases or impairments could help identify problems related to subacute care. For example, a review of patients' health status and functional abilities in addition to their use of medical services might indicate whether longer hospitalizations, or specific patterns of inpatient or outpatient rehabilitative services were associated with better rates of recovery following specific types of surgery (for example, hip surgery). Gathering information on subacute and institutional care as well as basic inpatient and physician services could also be useful for assessing the interrelationships among Medicare and Medicaid-covered services, including effects of coverage policies on the use, costs, and outcomes of care.

Longitudinal studies designed to identify variations in medical procedures and treatment plans are often conducted for targeted samples of cases. But nationally representative longitudinal data could identify trends in treatment patterns, use of services, and outcomes over time, highlighting problems that could be related to changes in the use of services resulting from modifications in reimbursement methods or the organization of health services.

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[5] D. Waldo and H. Lazenby, "Demographic Characteristics and Health Care Use and Expenditures by the Aged in the U.S.: 1977-1984," Health Care Financing Review (Fall 1984), p. 1.

Rather than focusing on specific known problems or the identification of "outlier" providers, studies of nationally representative populations can answer broader questions about trends in health care problems and the quality of medical care provided to the Medicare population as a whole. Comprehensive patient-level data of this type also would aid in evaluating possible differences in quality associated with fee-for-service, versus prepaid, medical care and in assessing the implications for patient outcomes of variations in the use of or availability of medical services in different regions or localities.

The costs of developing epidemiological data on the full range of health care used by the Medicare population would vary according to the size of the sample(s), the nature of the data collection (for example, medical records abstraction, patient interviews), whether additional administrative or validation data were obtained, the frequency of data collection, and so forth. Based on the costs of current studies collecting extensive patient-level data, it is likely that a set of epidemiological studies addressing a range of issues such as those discussed here would cost several million dollars per year.

The usefulness of these data, both in terms of increased public accountability and for targeting future program changes, could make such expenditures worthwhile. We believe, however, that designing such studies should be carefully linked to a wider plan or program for developing needed information on quality of care in the Medicare program.

Concluding Observations

Addressing the measurement and methods issues discussed here—developing improved outcome measures, assuring that the best methods available are incorporated into medical record review protocols, and developing longitudinal data sources to analyze quality of care for all services received by Medicare beneficiaries over time—is hampered by a fundamental problem: There is no clearly defined strategy or organizational structure responsible for producing information on the quality of health care provided to Medicare beneficiaries or for developing the underlying methods and knowledge base.

In our preliminary report, we characterized two separate aspects of this problem.[6] First, while the coordination of Medicare quality review activities is assigned to HCFA, the responsibility for assessing quality of care across settings and for evaluating changes in levels of quality over time has not been clearly assigned to any unit within HCFA. Second, there is no clearly identified "organizational structure" within HHS for developing, coordinating, or disseminating information about either the methods and procedures for quality assessment or their findings. Our subsequent work has increased our concern about where and how this type of work can be done most productively. These issues are discussed in the next chapter.

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[6] U.S. General Accounting Office, Medicare: Preliminary Strategies for Assessing Quality of Care, GAO/PEMD-87-15BR (Washington, D.C.: July 1987).

Chapter 7

Developing a Medicare Quality Assurance Strategy

The research issues reviewed in the previous chapter are but one aspect of a long-term strategy to advance the state of the art in quality assurance. As noted in chapters 4, 5, and 6, current information and methods are inadequate to address the questions and tasks that the Congress has already posed. For example, although PRO review responsibilities are scheduled to expand to nonacute care settings, adequate methods to perform those reviews do not currently exist and the research underway may not fill the gaps quickly enough.

Similarly, existing information cannot characterize current levels of quality in a manner responsive to congressional interests. Beyond this, sound program management requires anticipating future instances in which information pertaining to quality will be required (perhaps in conjunction with proposed changes in the Medicare program) and creating a capacity to respond to those situations as they arise.

Developing a long-term strategy for quality assurance to meet currently known and future needs would require thinking through two sets of activities. The first pertains to basic methods development and includes advancing the knowledge base regarding (1) the specification of good clinical practice, (2) the incorporation of that practice into standards and quality assurance methods, and (3) the evaluation of incentives for practitioners to adopt such practice standards. These activities are essential to furthering quality assurance generally and are relevant to the Medicare program as well as to other public and private health care programs.

The second set of activities is specific to the Medicare program and includes (1) incorporating advances in the knowledge base into Medicare quality assurance efforts, and (2) monitoring their effectiveness. As discussed below, these two sets of activities require different perspectives, resources, knowledge, and skills. They do not necessarily need to be performed by the same organization, but should certainly be coordinated.

In this chapter, we review the requirements for accomplishing the activities described above, discuss organizational entities inside and outside the federal government engaged in relevant research, and delineate some pros and cons of alternative organizational configurations and funding sources.

Prerequisites for a Quality Assurance Research Strategy

Research and Development Knowledge Base

The current array of quality assurance methods reflects years of developmental efforts by HHS and by the health services research and medical education communities. Future work should build on this base, putting research resources to best use and furthering the state of the art, rather than reinventing it. The organization supporting quality assurance research needs a professionally trained multidisciplinary staff. Identifying research needs and setting priorities requires well-established ties to the health services and medical research communities, medical practitioners, and users of quality assessment methods. A strong peer review process is essential to ensure that only the best research applications are recommended for funding; funding decisions should be based primarily on scientific merit and substantive research priorities. Finally, the results of this research need to be carefully monitored, subjected to the scrutiny of the professional community, integrated with what is already known, and disseminated for use by individuals and organizations responsible for implementing quality review activities. This approach to review and funding should enhance the credibility and utility of the research and research findings.

Incorporating Advances Into Medicare

Adapting the findings of quality assurance research so that they can be implemented appropriately in the Medicare program also requires research and analytic skills, but of a different nature than those involved in conducting the initial research. Persons performing the translation function must understand the strengths and limitations of the methods and findings of the initial research, as well as the structure and operations of the Medicare program. Tailoring research findings to meet Medicare programmatic needs may require some modification and further testing before they are integrated into ongoing quality review activities. Evaluating the effects of quality assessment efforts, as well as levels of quality attained, again requires research and operational expertise, but also an objectivity that allows separating empirical evidence of success or failure from a desire to see the program work effectively. Finally, it may be necessary to develop better institutional mechanisms to balance the need to curtail Medicare coverage and utilization for cost control reasons against quality assurance findings that may indicate the need for increased expenditures in certain areas.

Organizations Currently Involved in Quality-Related Research

Certain components of quality of care research activities are currently performed by a variety of federal and private organizations. At the federal level, both executive branch and congressional agencies are involved. In the discussion below, we outline the relevant research activities and responsibilities of these organizations. Developing a comprehensive quality assurance system to support the Medicare program will require consideration of the unique attributes of these organizations and the activities that each can best perform, specification of responsibilities and accountability, and the development of formal coordination mechanisms. We discuss organizational alternatives, but because of the complex trade-offs involved, we do not recommend a specific configuration.

HHS Quality of Care Research Efforts

Most Medicare-relevant quality of care and quality-related studies in the federal government are conducted at HCFA and three other HHS agencies: the National Center for Health Services Research and Health Care Technology Assessment (NCHSR&HCTA), the National Institutes of Health (NIH), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Appendix VI includes an overview and analysis of major HHS studies related to measuring or assessing quality of care in the Medicare program through the end of fiscal year 1987.

Health Care Financing Administration

Within HCFA, the Office of Research and Demonstrations (ORD) supports over 200 research, evaluation, and demonstration projects that focus on health care expenditures, reimbursement, coverage, eligibility, and management alternatives under Medicare and Medicaid. Studies also examine program effects on beneficiary health status, access to services, utilization, and out-of-pocket expenditures, as well as the behavior and economics of health care providers and the overall health care industry. Within ORD, these activities are carried out by the Office of Research, which supports data collection efforts and research on the above topics, and the Office of Demonstrations and Evaluation, which manages pilot programs and experiments that test new ways of delivering and financing Medicare and Medicaid services.

As of July 1987, ORD had a total of 174 staff (141 professionals) and an extramural research and demonstrations budget of $28 million. The Director is a career Senior Executive Service appointee. Applications for grants and cooperative agreements are reviewed for technical merit by specially created review groups of both nonfederal experts and HHS staff. They are not formally constituted review panels in the NIH/NCHSR tradition (see below). Rather, they are newly formed for each review cycle, and ORD staff rotate the responsibility for chairing the groups, although an attempt is made to achieve some continuity in review groups' membership over time.

Contract proposals are reviewed according to the usual government procurement process. The criteria for funding new projects include consideration of the scores and recommendations of the technical review panels, but HCFA research and policy priorities are also taken into consideration. The Administrator of HCFA can consider all grant applications for funding, and not just those judged as technically acceptable and rated highly by the review panels. The policy relevance of the proposed studies, as judged by HCFA senior staff, and the availability of resources, therefore, play a role in funding decisions.[1]

While some studies funded by ORD are primarily designed to assess or develop methods to measure quality of care, most studies develop information the Medicare program needs to refine DRGs and extend prospective payment methods to other services. In some cases, these studies are designed to respond to specific congressional mandates. For example, The Omnibus Budget Reconciliation Act of 1986 mandated that HCFA examine alternative approaches to developing severity adjustments and make recommendations for refining the DRG payment methodology to better reflect differences in case severity. Other studies, such as the comparison of cost and quality of nursing home care in hospital-based and free-standing facilities, will provide information needed to develop appropriate methods of paying for these services prospectively.

Developmental work on the assessment of quality of care has also been conducted within ORD as part of the evaluation of demonstration projects, such as the assessment of Medicare HMOs operating under waivers. As discussed in appendix VI, HCFA's congressionally mandated

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[1] A discussion of ORD's proposal review and the funding process is presented in J. Hawes, "The Management of Demonstration Programs in the Office of Research and Demonstrations, Health Care Financing Administration," in T. Glennan, et al., Case Studies of the Management of Demonstration Programs in the Department of Health and Human Services (Santa Monica, Calif.: The Rand Corporation, May 1986), pp. 43-6. These issues are also being examined by GAO.

assessment of the impact of the prospective payment system includes a large-scale study of both health care outcomes based on administrative data and of the process and outcomes of care through focused medical record reviews for selected medical conditions. These studies have involved extensive measurement and methods development.

ORD has not, however, become extensively involved in the evaluation of quality assessment methods employed in the PRO program, nor in the analysis of quality-related data generated by the PROS. ORD and the Health Standards and Quality Bureau (HSQB), which oversees the PRO program, have jointly funded a study to generate severity indicators from clinical information on patient medical records. Otherwise, quality of care research conducted in ORD and the oversight of quality review activities performed in HSQB (for PROS and SuperPRO) and in the Bureau of Program Operations (for carriers and intermediaries) are essentially independent operations.[2] The HSQB outcomes analyses that help target PRO review activities are being developed with only loosely structured coordination with ORD, which is conducting its own studies of outcomes. HCFA has convened meetings of experts on outcomes analysis, and there are informal contacts between HSQB and ORD researchers. We are not aware, however, of any formal system or structured research agenda within HCFA to evaluate and compare the various quality assurance methods used in HCFA programs along the lines suggested in previous chapters.

The National Center for Health Services Research and Health Care Technology Assessment

Created in 1968, NCHSR&HCTA is the federal government's only general-purpose health services research agency. Located within the Public Health Service, its mission is not directly linked to the programmatic needs of any federal health care delivery or financing program.

The Center's general legislative authority states that to the extent possible, the Secretary shall rely on the Center to coordinate all health services research, evaluation, and demonstration supported through HHS. In addition to studies in the areas of health manpower and health facilities, the Center may undertake and support projects related to the accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and health systems. In 1982, some responsibilities of the former National Center for Health

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[2] Given their program integrity purpose, the studies of quality of care conducted by the HHS Office of the Inspector General are also independent of ongoing ORD research efforts.

Care Technology were transferred to NCHSR&HCTA. Part of these responsibilities involves advising HCFA on coverage questions that arise in the Medicare program. This continues a tradition of relying on the Public Health Service to provide scientific and medical advice in the management of the Medicare and Medicaid programs. The coverage and technology assessment activities, which include collecting, analyzing and synthesizing medical and scientific evidence and professional opinion, require frequent contact between the Center's Office of Health Care Technology Assessment and NIH, the Food and Drug Administration, and the Council of Medical Specialties Societies, as well individual specialty societies and clinical researchers.

In fiscal year 1987, NCHSR&HCTA had a total of 139 staff (71 professionals) and a total budget of about $36 million (including $16 million from the Public Health Service's evaluation funds to support the National Medical Expenditures Study). The budget for extramural research was about $10 million. The director of the Center is a career Senior Executive Service member appointed by the Secretary of HHS. New legislation to reauthorize NCHSR&HCTA was passed in 1987 (Public Law 100-177). In addition to increasing the Center's authorization ceiling, the legislation prohibits altering the administrative relationship between the Center and the Office of the Assistant Secretary of Health as in effect during fiscal year 1986.

Following the NIH model, NCHSR&HCTA relies heavily on the peer review process and close interaction with medical professionals and technical experts; approximately 400 persons in disciplines including medicine, biomedical research, nursing, and a variety of social sciences have consultant agreements with the Center. Applications for research grant support are reviewed for technical and scientific merit by formally constituted peer review panels composed entirely of nonfederal researchers chosen for their substantive expertise. The review panels are chaired by full-time executive secretaries who are federal employees. Contract proposals are reviewed according to the usual government procurement process. The 1987 legislation (Public Law 100-177) requires that grants and contract applications exceeding $50,000 undergo peer review and that only those that have been recommended for approval by a peer review panel be funded.

In addition to research proposals targeted to specific areas, such as medical practice variations and patient outcomes, NCHSR&HCTA encourages investigator-initiated projects through both the general grants solicitation and its small grants program. The latter provides support (up to

$50,000) for innovative approaches to addressing "significant problems in the delivery of health services," for exploratory and pilot projects and for work fostering the design and testing of new research methods and techniques.

Between 1970 and 1975, the Center was actively involved in a utilization and quality review demonstration program that included the establishment of area-wide Experimental Medical Care Review Organizations (EMCROS). These organizations were the "prototypes" for the first generation of Medicare and Medicaid peer review organizations, the Professional Standards Review Organizations (PSROS). Despite sizable budget cuts (funding was reduced from $65.4 million in 1973 to under $30 million by 1979), the Center continued to focus on quality of care issues until the early 1980s. In several instances the Center supported the initial research in areas that were subsequently developed by others. For example, NCHSR supported early development of the computer stored ambulatory record system, which was further developed elsewhere as a management and quality monitoring tool (see appendix VI). The initial work on DRGS was supported by NCHSR and later picked up by HCFA.

In 1979-1981, the Center directed 13 to 15 percent of its approximately $25 million research budget to quality of care studies. The Center has continued to support research in quality of care, but at reduced levels. Much of this work has focused on helping clinicians with decisionmaking under conditions of medical uncertainty, rather than on developing prescriptive quality standards. Extramural projects examining quality of care issues are listed in appendix VI.

The Omnibus Budget Reconcilation Act of 1986 mandated that the Secretary of HHS establish a patient outcome assessment research program to be administered by the Center. To support this research, the law authorized the transfer to the Center of $4 million for fiscal year 1987 and $5 million in fiscal years 1988 and 1989 from the Medicare hospital insurance trust fund, and $2 million for fiscal year 1987 and $2.5 million for fiscal years 1988 and 1989 from the Medicare supplementary medical insurance trust fund.

The research program is intended to "promote research with respect to patient outcomes of selected medical treatments and surgical procedures for the purpose of assessing their appropriateness, necessity and effectiveness," and requires that the program include (1) reorganization of part A claims data to facilitate research, (2) assessments of the appropriateness of admissions and discharges, (3) assessments of the extent of professional uncertainty regarding efficacy [of treatments or procedures], (4) development of improved methods for measuring patient outcomes, and (5) evaluation of the effects on physicians' practice patterns of dissemination to physicians and peer review organizations of the findings of its research (listed in points 2 to 5 above). The law also specifies that, in cooperation with appropriate medical specialty groups, the Center shall disseminate the findings of this research as widely as possible, including to Medicare peer review organizations.

As of August 1987, however, the trust fund allocations to conduct the outcomes research specified in the 1986 budget act had not been released to the Center, and grants intended to be funded by this transfer had not been awarded (although several studies addressing this issue were funded out of the Center's basic extramural research budget). HHS disputed the need to transfer Medicare funds to the Center and argued that a plan for coordinating research already being funded met the requirements of the law. ASPE, in cooperation with NCHSR&HCTA and HCFA, coordinated the drafting of an agency-wide plan for meeting the legislative requirements with ongoing work. The details of this plan were not available as of November 1987. Public Law 100-203, passed in December 1987, appropriated about $1.9 million for outcomes assessment research at the Center for fiscal year 1988.

National Institutes of Health

The National Institutes of Health have very broad authority to undertake research related to basic biomedical and clinical questions. This work is deeply rooted in the traditions of peer review and consultation with experts. NIH has not, for the most part, focused on the types of issues that require the application of health services research methods or techniques.

Although neither we nor HHS identified any studies ongoing at NIH that are directly addressing Medicare quality of care issues, there are clearly important links between NIH studies of clinical efficacy and quality of care.[3] There are also close links between the methodologies being employed to develop consensus about the efficacy of medical procedures and quality assessment research. The methodology for generating explicit case review criteria developed as part of the Rand Corporation's quality of care reviews, for example, is closely related to the consensus methods used at NIH for assessing treatment modalities and medical technologies.[4]

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[3] The National Cancer Institute is assessing the quality of life of cancer patients. None of the NIH projects we identified, however, directly addressed quality of care assessment in terms of the processes or outcomes of care in a manner that was immediately relevant to quality measurement in the Medicare program, and we have not included any of these projects in our discussion of quality of care research in appendix VI.

Within NIH, the Office for Medical Applications of Research has primary responsibility for translating the results of biomedical research into knowledge that can be used to improve the day-to-day practice of medicine.

HHS Office of the Assistant Secretary for Planning and Evaluation

The primary function of the Office of the Assistant Secretary for Planning and Evaluation is the coordination of planning and evaluation activities throughout HHS, particularly as they support the broader HHS policy agenda. Overall, ASPE has a total of about 70 professional staff working on policy, planning, or evaluation issues. About half work either in the health planning division or on long-term care or other health-related issues.

In 1987, ASPE reported to us that approximately one full-time staff equivalent worked on quality of care issues. ASPE does coordinate quality of care-related work and was the central figure in responding to the legislative mandate to support outcomes research, as discussed above. However, ASPE's ability to influence the research agendas of particular HHS agencies is limited by the fact that other agencies have their own legislative authority and mandates.

ASPE funds studies when information is needed for policymaking. The Aftercare study described in appendix VI represents a fairly large effort jointly planned and funded by ASPE and HCFA to address important questions about the need for and access to appropriate posthospital care for Medicare beneficiaries. It examines issues that were considered to be important by the executive branch (as well as Congress), but were inadequately addressed in HCFA research and evaluation activities at the time the study was initiated.[5] ASPE is not, however, charged with any primary responsibilities for conducting research or evaluation in support of the Medicare program and does not have authority to support an ongoing program of health services research.

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[4] A. Fink, et al., "Consensus Methods: Characteristics and Guidelines for Use," American Journal of Public Health, vol. 74, no. 9 (September 1984), pp. 979-983.

[5] U.S. General Accounting Office, Post-Hospital Care: Efforts to Evaluate Medicare Prospective Payment Effects Are Insufficient, GAO/PEMD-86-10 (Washington, D.C.: June 2, 1986).

Other Congressionally Mandated Quality-Related Activities

Congressional concern about the quality of care provided to Medicare beneficiaries has led to a series of studies by congressional agencies. Ongoing GAO studies are examining quality-related issues in home health care and HMOs, as well as the effectiveness of PRO efforts to identify and correct possible quality of care problems. The Office of Technology Assessment is studying whether indicators of quality of care can be developed to guide consumers and private sector payers in selecting health care providers and facilities. The Congressional Research Service has compiled comprehensive descriptive information on PRO activities and operations, including quality review activities. Together, these studies should provide fairly extensive information about the possibilities for developing useful information on quality of care in Medicare services, as well as the limitations of current systems and methods.

The Prospective Payment Assessment Commission

Congress has given a fairly wide quality of care evaluation mandate to the Prospective Payment Assessment Commission. Established under the Social Security Act Amendments of 1983 (Public Law 98-81), which introduced Medicare prospective payment for inpatient hospital services, the commission is composed of independent experts appointed by the Director of the Office of Technology Assessment, and reports its findings to the Congress and to HHS. Its original mandate focused on recommendations to adjust the classification and weighting factors used to establish DRG payments. This requires the commission to analyze changes in treatment patterns or methods of treatment, including the introduction of new technologies, and any other factor that could affect the average cost of providing care for specific diagnostic groups.

Subsequently, the commission's mandate was broadened to evaluate the effects of prospective payment on the American health care system as a whole. In response, the commission has developed an analytic agenda for addressing quality of care issues. In 1986, it initiated a study to review the availability, provision, and cost of care in a hospital after the acute portion of the hospital stay has been completed. A second study focused on possible adverse outcomes for specific groups of beneficiaries who may be at particular risk with respect to quality of care.[6] A third study examined PROs' role in denials of inpatient care, and the commission reviewed hospitals' intramural quality assurance programs. The commission also plans to expand its analyses of regional variations in medical practice to include ways of using this information in making decisions about the appropriateness of DRG payment rates. The commission is careful to point out, however, that developing standards regarding appropriate rates of surgery or procedures is not within its mandate. Furthermore, its quality-related studies have been designed to address specific policy-relevant questions. The commission does not have authority to support research to develop or evaluate improved quality assurance methodologies.

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[6] The commission has identified three groups, frail beneficiaries (based on age and clinical status), disabled Medicare beneficiaries, and Medicare beneficiaries also eligible for Medicaid, as particularly vulnerable groups.

Commission reports have noted the possible development of quality of care problems in response to new PPS financial incentives and the deficiencies in information available to monitor potential problems. Its 1987 report to HHS specifically recommended that a comprehensive evaluation of the PRO program be conducted, noting that HCFA's program for validating PRO decisions via the SuperPRO "does not substitute for a comprehensive evaluation of the extent to which PROs are identifying, assessing, and correcting problems related to quality of care."[7]

The Institute of Medicine

The Omnibus Budget Reconciliation Act of 1986 requires HHS to arrange for a major study to design a strategy for reviewing and ensuring the quality of care for which payment can be made under Medicare. The legislation specifies eight items to be addressed in this study (without excluding others):

1. identifying the appropriate considerations which should be used in defining "quality of care";

2. evaluating the relative roles of structure, process and outcome standards in assuring quality;

3. developing prototype criteria and standards for defining and measuring quality of care;

4. evaluating the adequacy and focus of the current methods for measuring, reviewing, and assuring quality of care;

5. evaluating the current research on methodologies for measuring quality of care and suggesting areas of research for further progress;

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[7] Prospective Payment Assessment Commission. Report and Recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1987. (Washington, D.C.) p. 50.

6. evaluating the adequacy and range of methods available to correct or prevent identified problems with quality of care;

7. reviewing mechanisms available for promoting, coordinating, and supervising at the national level quality review and assurance activities; and

8. developing general criteria which may be used in establishing priorities in the allocation of funds and personnel in reviewing and assuring quality of care.

The 1986 budget stipulates that the study plans should ensure that consumer and provider groups, peer review organizations, the Joint Commission on the Accreditation of Healthcare Organizations, hospitals, professional societies, and private purchasers are consulted. HHS was required to request an application for conducting the study from the National Academy of Sciences, acting through its appropriate unit. The Institute of Medicine, which operates under an Academy charter to examine policy matters pertaining to health, submitted an application to HCFA to conduct the study in July 1987. The application was accepted and the study is now underway. A final report is due to the Congress on January 1, 1990.

Organizing Quality Assurance Research, Evaluation, and Operations

The information presented to this point illustrates that many relevant research and evaluation activities pertaining to quality assurance in the Medicare program are ongoing within and outside HHS. These activities are not, however, well coordinated, nor is there a systematic strategy for identifying future needs and initiating essential work to meet those needs. Congress acknowledged this by requiring in the 1986 budget act that the Secretary of HHS designate an office with responsibilities for coordinating studies relating to the quality of care for Medicare and Medicaid, including the assessment of the feasibility and cost of alternative studies, overseeing access to needed data, and maintaining a clearinghouse for public and private sector studies. ASPE has been assigned this responsibility.[a] Coordinating quality of care studies and information, however, is only a first step in developing a quality assurance system.

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[a] ASPE began assembling an inventory of quality of care studies in February 1987.

A number of informal proposals for creating a research and evaluation program have been offered by health services research experts.[9] These reflect a general consensus that there is no research base to guide physicians in making decisions about the efficacy of alternative approaches to providing care or for determining how to translate established clinical practice into federal policy for ensuring the appropriateness and quality of health care services.[10] These proposals also point to a number of issues and trade-offs that must be addressed in structuring and implementing such a program.

One basic consideration is the need to coordinate closely with the clinical research and technology assessment communities, so that available information on the efficacy and effectiveness of medical procedures and treatments can be incorporated into quality review protocols. A related issue is identifying, validating, and updating information on optimal patterns of clinical practice and standards of care as it emerges from clinical research, so quality assurance criteria remain current. This requires a long-term commitment to developing a knowledge base, which will quickly lose its value if it is not continually updated.

To monitor quality and evaluate the effects of quality assurance, access to and coordination with HHS data gathering and data analysis operations is necessary. Evaluators will need to use National Center for Health Statistics, NCHSR&HCTA, and Medicare data. They may also need direct access to these data, for example, to conduct studies assessing the usefulness of changing billing systems, screening algorithms, data verification procedures, and the like. Historically, it has been difficult for researchers outside HCFA to use Medicare data because of the size and complicated organization of the data systems. Privacy issues are also important considerations. The redesign of the Medicare data system may alleviate some of these problems, but the close cooperation of Medicare data processing divisions will be very important.

The potential for overlapping and possibly conflicting objectives and responsibilities also needs to be considered. Quality of care objectives may sometimes coincide with cost-containment objectives, as in the case of protecting beneficiaries from the cost and dangers of unnecessary or inappropriate treatment. But the possibility cannot be dismissed that containing costs could lead to withholding needed or appropriate forms of medical care. The tension between utilization review and quality review activities becomes particularly visible when review activities are evaluated on the basis of how much money is recovered from providers' billings for uncovered services.[11]

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[9] See, for example, R. H. Brook and K. N. Lohr, "Efficacy, Effectiveness and Quality: Boundary-crossing Research," Medical Care, May 1985, pp. 710-22.; J. P. Bunker, et al., "Evaluation of Medical-Technology Strategies: Proposal for an Institute for Health-Care Evaluation," New England Journal of Medicine (March 18, 1982) pp. 687-92, and A. S. Relman, "Assessment of Medical Practices: A Simple Proposal," New England Journal of Medicine (July 17, 1980), pp. 153-4.

[10] O. R. Bowen, "Shattuck Lecture—What is Quality of Care?," New England Journal of Medicine (June 18, 1987), p. 1579; D. M. Eddy, "Clinical Policies and the Quality of Clinical Practice," New England Journal of Medicine (August 5, 1982), pp. 343-7.

In making coverage decisions, the Medicare program needs to examine the effectiveness and other economic considerations (for example, possible effects on the volume or distribution of services) of a growing number of new technologies. But efforts that direct or focus scientific research to answer such policy questions have been perceived as threatening by the medical community. Making decisions about what technologies Medicare will or will not pay for has been perceived as government dictating how medicine ought to be practiced. Strong opposition from NIH as well as the professional medical and medical devices communities were, in the opinion of some experts, key factors in the 1981 dismantling of the National Center for Health Care Technology Assessment.[12] Parallels could arise with respect to the development and introduction of methods for measuring quality of care in the Medicare program.

The level of effort that would be involved in creating a structure for quality of care research and evaluation activities would be substantial, and it is not likely that these activities could be easily absorbed into any ongoing program. Adding these responsibilities to those of an established organization would, however, reduce start-up costs. The actual cost would depend on the scope of activities involved. As noted above, the Congress authorized about $6 million per year for a program to develop an outcomes assessment research program. Creating a broader system for generating, refining, and testing process-related criteria used in medical records review would add to program costs, as would initiating epidemiological studies such as those discussed in chapter 6. Prioritizing, coordinating, and integrating research findings to be useful for ongoing quality review activities are all functions not systematically performed at present by any agency.

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[11] This tension surfaced, for example, in testimony before the House Subcommittee on Health and the Environment, Committee on Energy and Commerce, on October 26, 1987, when a spokesman for the American Medical Association, William R. Felts, MD., stated that "While the new PRO contracts purport to place increased emphasis on quality issues, a widespread perception continues to exist, and is growing among physicians, that the PRO program emphasizes cost containment often at the expense of the health of Medicare beneficiaries."

[12] See, for example, D. Blumenthal, "Federal Policy Toward Health Care Technology: The Case of the National Center," Milbank Memorial Fund Quarterly/Health and Society vol. 61, no. 4 (1983), and S. Perry, "Special Report: The Brief Life of the National Center for Health Care Technology," New England Journal of Medicine (October 21, 1982).

Stable funding for such an undertaking is essential if continuing progress is to be expected. Within HCFA, budgets for research in general have been fairly tight. ORD's funding was cut from $28 million in fiscal year 1987 to $26.8 million in fiscal year 1988. Funding for NCHSR&HCTA quality of care activities has fluctuated considerably due to budgetary constraints and changing research priorities within HHS. Targeted funding for quality of care research—conducted within or outside HHS—would probably be allocated for a fixed time period, which might lead to problems of continuity if the program were not reauthorized. Thus, it would be critical that funding for an extensive quality of care effort be protected from additional budgetary pressures and potential diversion to research on other topics.

There are trade-offs in structuring a formal program for quality assurance research and evaluation. Placing it wholly within HCFA could provide efficiencies, both in start-up costs and access to data and the decisionmaking process, but also could present significant problems in terms of generating the support and trust of the professional medical communities. Locating this program within the Public Health Service, as part of the health services research and technology assessment program already in place at NCHSR&HCTA would alleviate some problems of perceived conflict of interest (related to HCFA's need to control Medicare program costs). It might also provide greater opportunities for interaction with the research and professional communities. However, past fluctuations in the Center's budget raise questions about whether the Center can maintain the level of support needed to sustain a large-scale research and evaluation program.

Creating a new entity within NIH is another option. Although it might provide an opportunity for a "fresh start," this option would clearly be expensive. More important, NIH has not historically devoted any substantial proportion of its resources to policy-related health services research; the tradition of basic research may conflict with the need to focus on payment, coverage, and quality issues that are inextricably linked to health care delivery and financing.

Table 7.1: Advantages and Disadvantages of Placing Comprehensive Quality Assurance Program in Existing Organizations

Organization	Advantages	Disadvantages
HCFA	Programmatic needs apparent; should increase relevance of quality assurance research Familiarity with and access to data	Weak tradition of sound peer review of research proposals Funding decisions driven by policy priorities, sometimes in conflict with technical merit of proposed research Potential conflict between quality of care needs and cost control and coverage decisions Strained relations with professional communities
NCHSR&HCTA	Strong tradition of sound peer review of research proposals Historic involvement in quality assurance research and development from diverse perspectives Experience in advising HCFA on coverage issues and cooperative research efforts Good access to health services, clinical research, and medical professional communities	Indirect access to HCFA data Indirect links to HCFA program issues Unstable budget history; instability of research funding
NIH	Strong tradition of research support and sound peer review of proposals Visibility, stability, and relative autonomy Ready access to clinical researchers and medical professional community	Historic disinterest in health services research Potential conflict between incentives to develop new technologies and the need to determine their effectiveness and establish practice standards Indirect access to HCFA data Indirect links to HCFA program issues
ASPE	Organizational location should facilitate access to relevant agencies in HHS Responsible for coordinating planning and evaluation activities	Weak tradition of peer review of research proposals Limited influence over other research funding agencies with their own staff and budget Limited experience with health services research Indirect access to HCFA data Indirect links to HCFA program issues Authority to fund research limited to specific topics or immediate research needs

(continued)

Organization	Advantages	Disadvantages
Independent agency or public or private organization	Easy access to medical research and professional communities	Research funding potentially limited to immediate policy questions
	Freedom from administrative constraints of executive branch	Weak tradition of peer review of research proposals
	May be able to raise private funds	Questionable ability to directly influence executive branch operations
		Limited public accountability
		Funding generally time-limited; stability over time questionable
		No direct access to HCFA data

Placing a quality assurance research and evaluation program outside HHS involves similar trade-offs. If this entity were developed as an independent agency or a combined effort of the private and public sectors, it might attract broader support from medical professional societies and health industry groups. A joint public-private venture would be less dependent on federal funding. Both approaches might experience difficulty, however, in gaining access to federal data systems and ensuring an adequate understanding of the programmatic needs and operations of the Medicare program. Furthermore, ensuring long-term stability could be difficult in the absence of permanent authority or funding commitments. Whether an independent agency could be integrated sufficiently into the policymaking process to effect changes in the Medicare program also needs to be considered, along with the issue of public accountability. It may be preferable to divide these responsibilities among two or more organizations, based on their comparative advantages. Thus, the knowledge generation and methods development might be assigned to one entity, while activities specific to the quality assurance requirements of Medicare and other programs could be assigned elsewhere. In table 7.1, we summarize the pros and cons of organizing a comprehensive program for quality assurance in existing organizations, highlighting the issues discussed above.

Conclusion

Current systems for reviewing Medicare services, assessing the extent or distribution of quality of care problems, and developing methods for measuring and monitoring quality of care are not designed to meet current or future policy and program evaluation needs. To ensure that individual covered services are provided appropriately and meet professional standards, the first priorities should be to improve current HCFA data systems, to document the effectiveness of current review methods, and to determine how program data can be used to provide better information on quality of care.

To identify broader problems in the Medicare population that may be associated with poor health care outcomes or the unnecessary or inappropriate use (or nonuse) of Medicare services, and to develop improved quality assurance methods that reflect changing clinical and reimbursement practices, a more comprehensive research and development program is required. This involves drawing on resources outside HCFA, including the clinical expertise, research, and methodology skills found in the Public Health Service and in the wider medical and health services research communities. It also requires the development of an organizational structure to facilitate the incorporation of emerging information on good clinical practice into the development of quality assurance methods, and ultimately, the integration of that knowledge into Medicare review activities.

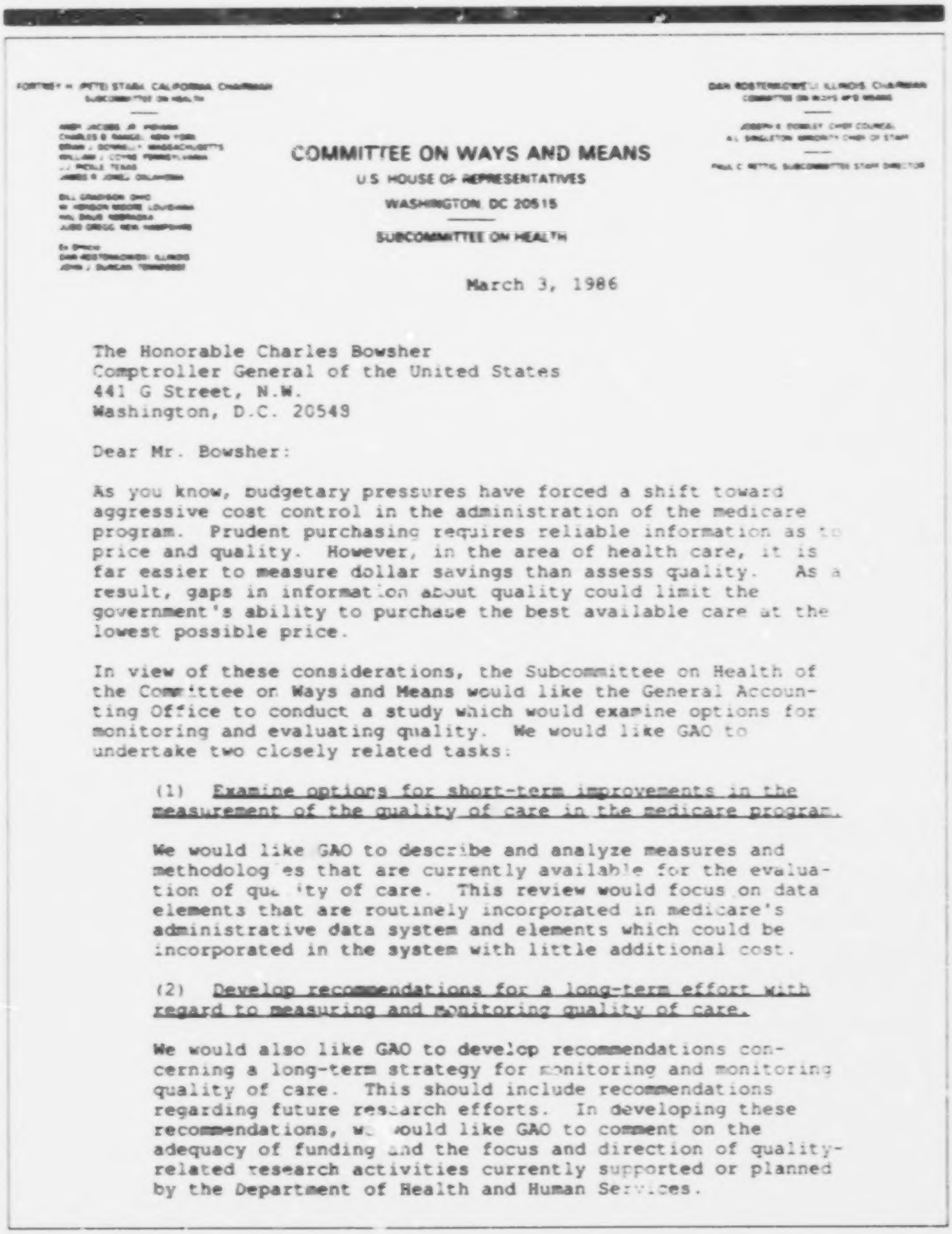
Matter for Consideration by the Subcommittee

The Subcommittee should consider developing legislative proposals to assign specific responsibilities to a new federal entity or existing entities designed to (1) develop, disseminate, and coordinate activities intended to advance the development of quality assurance methods and good medical practice, and (2) incorporate this knowledge into Medicare quality assurance efforts.

In their comments on the draft report, HHS did not concur with the concept of creating a new federal entity, stating it could result in a duplication of effort and inadequate communication. The agency stated, however, that improvements in internal coordination would be considered. In our discussion of alternative locations, we considered several existing agencies within HHS and did not mean to imply that responsibility should be given to a new office or agency, although that is an option. We have added the word "existing" to the phrase "new federal entity or existing entities" to clarify our intent. Nevertheless, the key point remains unchanged: There is no office or formal program in HHS charged with responsibility for basic research and development of quality assurance methods that would bridge the gap between clinical research and ongoing quality assurance programs in the manner we have specified.

We have briefly outlined five possible locations for quality assurance research and development activities. Each offers advantages and disadvantages; any configuration would require more funding than is currently being spent. However, the difficulties involved in structuring a quality assurance research and evaluation program do not, in our opinion, outweigh its potential benefits. Such an initiative would be an essential first step in developing an improved quality review system that can safeguard the health care of Medicare bencficiaries.

Request Letter



COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

March 3, 1986

The Honorable Charles Bowsher
Comptroller General of the United States
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

As you know, budgetary pressures have forced a shift toward aggressive cost control in the administration of the medicare program. Prudent purchasing requires reliable information as to price and quality. However, in the area of health care, it is far easier to measure dollar savings than assess quality. As a result, gaps in information about quality could limit the government's ability to purchase the best available care at the lowest possible price.

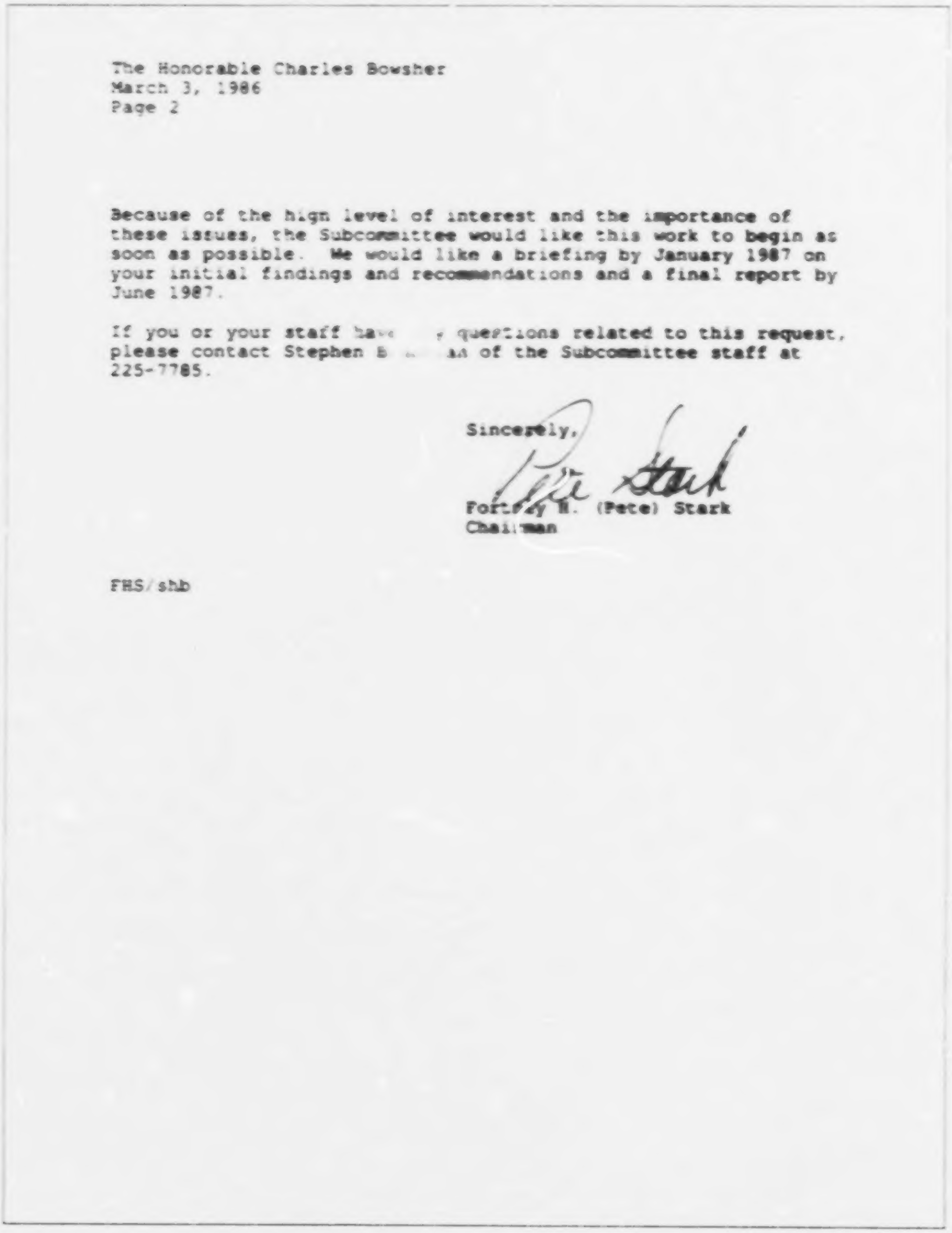
In view of these considerations, the Subcommittee on Health of the Committee on Ways and Means would like the General Accounting Office to conduct a study which would examine options for monitoring and evaluating quality. We would like GAO to undertake two closely related tasks:

(1) Examine options for short-term improvements in the measurement of the quality of care in the medicare program.

We would like GAO to describe and analyze measures and methodologies that are currently available for the evaluation of quality of care. This review would focus on data elements that are routinely incorporated in medicare's administrative data system and elements which could be incorporated in the system with little additional cost.

(2) Develop recommendations for a long-term effort with regard to measuring and monitoring quality of care.

We would also like GAO to develop recommendations concerning a long-term strategy for monitoring and monitoring quality of care. This should include recommendations regarding future research efforts. In developing these recommendations, we would like GAO to comment on the adequacy of funding and the focus and direction of quality-related research activities currently supported or planned by the Department of Health and Human Services.



The Honorable Charles Bowsher
March 3, 1986
Page 2

Because of the high level of interest and the importance of these issues, the Subcommittee would like this work to begin as soon as possible. We would like a briefing by January 1987 on your initial findings and recommendations and a final report by June 1987.

If you or your staff have any questions related to this request, please contact Stephen [illegible] of the Subcommittee staff at 225-7785.

Sincerely,

Pete Stark

Fortney H. (Pete) Stark
Chairman

FHS/shb

Appendix II

Consultant Panel Members

In selecting consultants for this review, we sought individuals who could address quality assessment issues from a variety of perspectives, including clinical medicine, health services research, utilization and quality review, health care administration, and policy.

We also wanted individuals familiar with all aspects of the Medicare program as it affects various health care settings, including skilled nursing facilities and home health services as well as hospital and physician services, and individuals knowledgeable about the needs and interests of Medicare beneficiaries.

With the advice of health services researchers and medical care experts from a variety of national organizations, including the Institute of Medicine, the National Center for Health Services Research and Health Care Technology Assessment, and the American Medical Peer Review Association, we drew up a list of potential consultants, all of whom agreed to serve.

Our consultant panel members were:

Robert Brook, M.D.
Senior Health Services Researcher
The Rand Corporation
Santa Monica, California

Earl David Buchanan[1]
Executive Director
Utah PRO
Salt Lake City, Utah

Margaret Cushman
President
VNA Group, Inc.
Plainville, Connecticut

Frederick Dettman, M.D.
Medical Director
Wisconsin Peer Review
Milwaukee, Wisconsin

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[1] Currently, Director, Quality Assurance Program, Hospital Corporation of American, Nashville, Tennessee

Avedis Donabedian, M.D.[a]
Nathan Sinai Distinguished Professor
Department of Health Services Management and Policy
School of Public Health
University of Michigan
Ann Arbor, Michigan

Richard Farmer, M.D.
Chairman, Division of Medicine
Cleveland Clinic Foundation
Cleveland, Ohio

Judith Lave
Professor of Health Economics
University of Pittsburgh
Pittsburgh, Pennsylvania

Vita Ostrander
Immediate Past President
American Association for Retired Persons
Atlanta, Georgia

Bruce Sams, M.D.
Executive Director
Permanente Medical Group
Oakland, California

Marvin Shapiro, M.D.
Vice President for Medical Affairs
U.S. Administrators
Los Angeles, California

Peter Shaughnessy[a]
Director, Center for Health Services Research
University of Colorado
Denver, Colorado

Bruce Vladeck
President
United Hospital Fund of New York
New York, New York

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[a] Did not attend January 8-9, 1987, panel meeting.

Intermediary and Carrier Surveys

Much of our data about the efforts of intermediaries and carriers to assess the quality of medical care within the Medicare program were gathered through two surveys conducted in the fall of 1986, and a brief follow-up questionnaire in July 1987. In this appendix, we present selected analyses of those data.

Survey Focus

Computer screening of claims files for signs of quality of care problems, either from misutilization or underutilization, is generally not the responsibility of the intermediaries and carriers. This is not to imply that they are unsympathetic or uninterested in such screening, but under the present system, they are not compensated by HCFA for doing it.

The purpose of our questionnaires was to discover what information collected by the carriers and intermediaries as part of their normal processing of Medicare claims might be useful in assessing the quality of medical care. We wanted to document their typical level of effort and examine more closely any innovative or more active medical screening protocols.

Survey Participants

We obtained from the Health Care Financing Administration (HCFA) the names and addresses for all 54 Medicare part A intermediaries. A questionnaire was sent to each intermediary in November 1986; 52 completed questionnaires were returned. Of the two organizations who chose not to complete the questionnaire, one reported that it was no longer under contract as an intermediary.

We also obtained from HCFA the names and addresses of all 37 Medicare part B carriers. During the fall of 1986, each carrier was sent a copy of the carrier survey; 34 completed questionnaires were returned. Of the three organizations who chose not to respond, one reported that it was no longer under contract as a part B carrier.

In July 1987, we again contacted the 34 respondent carriers by telephone for a brief follow-up questionnaire. Thirty-two carriers gave complete answers to this second round of questions, and we received partial responses from the other two. Overall, 96.6 percent of the organizations that act as Medicare intermediaries and carriers returned completed questionnaires in the first round, and 94 percent of the participating carriers completed the telephone follow-up survey. All questionnaires were coded and entered into the data file used in the analyses presented in this appendix.[1]

Part A Questionnaire

Intermediaries are responsible for processing Medicare claims for most hospital-based services, as well as covered care in skilled nursing facilities, home health agencies, hospice care and comprehensive outpatient rehabilitation facilities. Under the prospective payment system of hospital reimbursement, however, responsibility for monitoring inpatient quality of care has been assigned to Peer Review Organizations (PROS). More than three quarters of the intermediaries reported no additional screening of inpatient hospital claims data for quality of care concerns. (See table III.1.)

Table III.1:Number of Optional Hospital Screens Used Per Intermediary

Number of screens used[a]	Number of intermediaries	Percent[b]
None	40	76.9
1	5	9.6
2	3	5.8
3	0	0.0
4	1	1.9
5	0	0.0
6	2	3.8
7	1	1.9
Total	**52**	**99.9**

[a] Mean = 0.65

[b] Total of 99.9 due to rounding

The most frequently used optional hospital prepayment screens address the medical necessity or appropriateness of services. Ten of the 52 respondents use this type of screen. Only two of the 52 reported screening for quality of care.

The intermediaries are chiefly responsible for ensuring the quality of services provided by skilled nursing facilities and home health care organizations. Sixty-three percent of the intermediaries do some optional screening of skilled nursing facilities, and 56 percent do some optional screening of home health agencies beyond what is mandated by HCFA. (See tables III.2 and III.3.) Medical necessity and appropriate level of care are the most frequently screened attributes in both settings.

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[1] For both the intermediary and carrier questionnaires, we interpreted a blank in a response category as an indication that the organization did not perform any of the activities referred to in the question.

Excessive lengths of stay in skilled nursing facilities, and excessive numbers of visits in home health care settings are the second most frequently screened elements.

Table III.2: Number of Optional Skilled Nursing Facility Screens Used Per Intermediary

Number of screens used[a]	Number of intermediaries	Percent[b]
None	19	36.5
1	7	13.5
2	10	19.2
3	3	5.8
4	3	5.8
5	3	5.8
6	2	3.8
7	2	3.8
8	3	5.8
Total	**52**	**100.0**

[a]Mean = 2.17

Table III.3: Number of Optional Home Health Agency Screens Used Per Intermediary

Number of screens used[a]	Number of intermediaries	Percent[b]
None	23	44.2
1	6	11.5
2	12	23.1
3	5	9.6
4	0	0.0
5	2	3.8
6	0	0.0
7	0	0.0
8	4	7.7
Total	**52**	**99.9**

[a]Mean = 1.67

[b]Total of 99.9 due to rounding

The majority of intermediaries (28 of 52) do not send to HCFA any of the information that they derive from their optional screens. The little information that is reported is usually directed to the HCFA regional office or to both the regional office and HCFA headquarters in Baltimore. Information is occasionally reported to the regional inspectors general or to some combination of these offices in no apparent pattern.

There is no single, consistent length of time the intermediaries keep the information collected through optional screens. Intermediaries reported keeping these data for as little as 6 months and as long as 84 months. Thirty-six months is the modal period for data retention.

Few intermediaries use their claims data to generate hospital or facility profiles. Only four reported profiling specific hospitals, four profiled skilled nursing facilities, and 5 of 52 profiled home health agencies. Only two intermediaries look at geographical variations in the facility profiles.

In summary, intermediaries do little optional quality of care screening for inpatient hospital claims. They more actively screen claims from skilled nursing and home health settings, but in most cases this takes the form of screening for potential overutilization of services.

Part B Questionnaire

Part B carriers are responsible for reimbursing health practitioners, medical labs, and medical supply companies on a reasonable-cost basis for most outpatient services. As part of the claims processing, carriers have the responsibility for reviewing their claims data for potential patterns of overutilization of services. At the time the survey was conducted, HCFA mandated that carriers perform 16 automated claims screens to identify the most frequently occurring inappropriate claims. However, we found that all but one of the carriers also voluntarily used additional optional prepayment screens, and most use postpayment screens as well. (See table III.4.) The total number of optional prepayment screens used by carriers ranged from 5 to 177, with the median carrier using 44 optional screens.

Table III.4: Types of Optional Screens Used by Carriers

Type of screen used	Number of carriers	Percent
Prepayment for excessive costs	31	91.2
Postpayment for excessive costs	27	79.4
Prepayment for excessive treatments	28	82.4
Postpayment for excessive treatments	22	64.7
Quality of care (other than above)	7	20.6

Almost all the carriers (31 of 34) stated that they do cost-benefit analyses of the mandatory and optional screens and report to HCFA the amount saved from denied or reduced reimbursements in cases that were first identified by each screen. As discussed in chapter 3, carriers must justify the use of screens for which less than 20 percent of suspended claims are denied.

We found that many carriers generate practitioner profiles from their claims data. Information on suspended or denied claims is the most frequently used datum for the practitioner profiles. Information about the causes of the suspended or denied claims is the second most frequently entered. However, information about aberrant rates of medical complications or mortality is rarely incorporated into the profiles, and information about legal actions brought against practitioners is seldom compiled. (See table III.5.)

Table III.5: Types of Information Carriers Incorporate Into Practitioner Profiles

Type of information	Frequency	Percent
Suspended or denied payments	26	76
Causes of suspension or denial	23	68
Legal actions	3	9
Complication rates	1	3
Mortality rates	1	3

Nineteen of the 34 carriers (56 percent) compile some information about geographical variations in practitioners' patterns of practice. However, this compilation is confined exclusively to comparisons of the number of procedures or services billed, which is required for the monitoring of area-adjusted payment rates. Variations in patient outcomes are not profiled. Carriers also do not include data on differences in severity of illness that might be factors in the variation of procedure rates. (See table III.6.)

Table III.6: Types of Information Carriers Include in Regional Variation Profiles

Types of information	Frequency	Percent
Numbers of procedures	19	56
Severity of patient conditions	0	0
Complication and comorbidity rates	0	0
Mortality rates	0	0

In a slight majority of the states (27 of 51), one organization contracts simultaneously with HCFA as both the part A intermediary and part B carrier. When this occurs, however, these functions are usually handled separately by two different data systems. Approximately one quarter of the carriers (8 of 34) reported that they can link cases that have claims in both data systems from the same episode of care. From the carriers' written comments, it appears that the main purpose of these linkages is to flag part B practitioner claims in cases where part A-covered services for the same patient have been denied or are under review. (See chapter

3 for a discussion of A/B data requirements.) Linking part A and part B claims in order to follow a patient across an illness episode—from an initial outpatient visit, through a period of hospitalization, to the end of a posthospital convalescence—is not part of any carrier's regular claims processing activity.

Seven of the carriers (21 percent) reported that they use optional screens specifically to identify indicators of poor quality of care. However, our analysis indicated that most of these screens flag the claims of health care practitioners who have previously been suspected of, or identified as making, excessive claims. Only one carrier's quality screens identify cases on the basis of questionable combinations of medical services or procedures.

Ten of the carriers reported that they either developed their own quality of care screening system, or acquired one from some outside commercial or professional source. From the descriptions of the systems, most involve medical professionals in either manually reviewing individual cases or drafting new overutilization screens. Only one carrier appeared to use computer algorithms to flag claims that might indicate quality of care problems unrelated to overutilization.

Unlike the intermediaries, all carriers report to HCFA some information they generate from their optional screens. However, there is no consistent pattern in which overutilization or quality of care information is forwarded, or on where the information is sent. Summary data—across cases, practitioners, and time periods--are more often reported, usually to both the regional HCFA office and to HCFA headquarters in Baltimore. Individual cases are infrequently reported, most often to a regional inspector general's office.

Summary of Initial Questionnaires

Intermediaries have little responsibility for monitoring the quality of care for most inpatient hospital services and do little optional screening of these claims. For other health care settings, however, where claims are still reimbursed on a case-by-case basis for reasonable and necessary expenses, intermediaries and carriers more actively screen claims for signs of overutilization. A few written comments included in the completed questionnaires indicate the sensitivity that some contractors feel about only performing the functions specifically assigned to them by HCFA. The following response from an intermediary was the most explicit on this point:

"Our [intermediary] budget includes funding only for duties which we are specifically instructed to perform. Unfortunately, since we are compelled to operate within the constraints of this budget we have been unable to assume review functions in addition to those mandated. We would be willing to pursue quality of care issues when appropriate funding is provided."

Supplementary Questionnaire

The supplementary questionnaire focused exclusively on whether carriers receive and analyze diagnostic data on part B claims. There are two ways that medical practitioners and other part B-eligible providers or suppliers can submit a bill to a Medicare carrier. The original billing procedure, still used for 65 to 70 percent of all part B claims, is to submit a HCFA form 1500 paper claim. There is a space reserved for ICD-9-CM diagnostic codes on the form 1500, but HCFA does not require that these diagnostic codes be entered. HCFA only requires that a narrative description of the nature of the patient's medical complaint be entered on the form.

All carriers collect at least some ICD-9-CM codes through a second, more recently developed claims submission method: the electronic media claims system. Under this system, providers have computer terminals in their offices through which they can directly enter a claim to the carrier's computer system. An electronic claim must include one or more ICD-9-CM diagnostic codes to identify the medical problems for which services were provided. All 37 carriers, in all 54 contract regions of the country, now receive at least some of their part B Medicare claims through the electronic system. The percentage of electronic claims volume ranges across regions from 7 to 59 percent, with the national average now approximately 30 percent. HCFA has set a national goal of 50 percent of claims submitted through the electronic media system and believes that is the maximum feasible limit of participation at the present time. Thus, ICD-9-CM codes are now included in at least one third of the part B claims volume, owing to electronic claims, and eventually 50 percent or more of the part B claims will have this information.

To develop more information about the feasibility and possible costs and benefits of adding ICD-9-CM diagnostic code data to all part B claims, we conducted a follow-up telephone survey of the carriers in July 1987. Our brief phone questionnaire was designed to find out what each carrier is now doing, voluntarily, with the diagnostic information included on provider bills, and how much of a burden it would be if they were to begin routinely collecting, keying, and reporting information about diagnostic information from all part B bills. The results of this brief survey are summarized in table III.7.

Table III.7: Carriers' Processing of the ICD-9-CM Diagnostic Codes Included in Paper Claims

Use ICD-9-CM codes	Number of carriers	Percent
Code only when present on forms	6	18
In all cases, convert narrative into codes when codes not supplied	10	29
Total	**16**	**47**
Do not use codes		
Could, but do not	9	26
Cannot, given present data base	9	26
Total	**18**	**53**

The 10 carriers that always translate the narrative descriptions into appropriate ICD-9-CM codes generally thought that the cost of keypunching these extra data is minimal, though most had never bothered to estimate the expense. According to one of the few carriers who did estimate, simply keying in submitted codes increased their keypunching costs by about 1 percent. Another carrier who looked into this issue concluded that the added cost amounted to a "couple of cents per claim." One carrier estimated that having its keypunchers manually convert the narrative description into ICD-9-CM codes increased its data-entry costs 2.5 percent. Another carrier reported that it had purchased a commercial software package to partially automate these translations.

Thirteen of these 16 carriers reported that they use the ICD-9-CM codes in diagnosis-driven screens. Ten of the thirteen believe that they recapture the added costs of keying in the ICD-9-CM codes through the savings derived from increased claims processing efficiency and better recognition of cases with potentially inappropriate billings. However, none had done a study to estimate the extent of these savings.

Eighteen carriers do not key in ICD-9-CM codes, even when they are present on the paper claims form. Nine of the 18 carriers (50 percent) have fields in their data bases reserved for the codes and could begin keying them in with only minor start-up costs. Three of these nine are in the process of testing the feasibility of collecting the codes.

There was a variety of opinions among these nine carriers about the costs and potential savings from using these codes. Six of the nine believed the increased cost of keypunching would be minor, while the other three disagreed. The nine carriers were even more divided about any potential savings from using these codes in diagnosis-driven screens. Three thought that significant savings could occur. Two were unsure if there would be any savings, and the remaining four were fairly certain that the expense involved could not be recaptured.

The other nine carriers who do not key in the ICD-9-CM codes do not have the software capability to do it, even if they wanted to. Most of these carriers thought that there would be significant expense involved in changing their software, and only one thought that any savings or benefit could come from making this costly change. Most are carriers in densely populated parts of the country.

Medicare carriers were not required to alter the data storage systems they had been using for paper claims when they began participation in the electronic media claims system, if they felt the software development would not be cost-effective. The result is that some carriers maintain two parallel data bases—one for electronic claims and one for paper claims. These carriers have developed various translator programs to merge the electronic claims into the dominant, paper claims data base. The translator program drops electronic data elements—including the ICD-9-CM codes—when the dominant data base has no data fields reserved for the additional information present on the electronic submissions. These carriers would have to alter their paper-based systems if they were required to begin collecting and storing ICD-9-CM codes for all their part B claims.

In our interviews with the carriers, we identified several potential problems that might complicate the uniform collection of ICD-9-CM codes from all part B claims. The first involves situations where practitioners enter multiple diagnostic codes for the same office visit. One carrier told us that 14 to 16 carriers use a particular commercial software package that can record no more than two diagnostic codes per claim. Several carriers told us this would not be a problem if practitioners restricted the codes they entered to those that were directly relevant to the procedures or services they were performing on that particular visit.

A potentially more difficult problem involves claims from labs and medical supply houses. We were told that these claims often do not have diagnostic codes, and carriers have trouble matching the services billed to medical problems treated in a specific office visit. Many carriers had doubts that these ancillary billers would be willing or able to get the diagnostic codes from the practitioners at the time that the tests or supplies were initially ordered and accurately pass them on to the carrier. However, medical supply companies must include diagnostic codes on their electronic claims, and some carriers are also requiring labs to use these codes when they submit electronic claims. Since they do collect and report codes for their electronic media claims business, these labs and medical supply houses should be able to routinely do it for all claims. The reliability of the diagnostic data would need to be verified, however.

In our opinion, the most difficult problem in uniformly collecting the diagnostic codes involves nonassignment cases, where beneficiaries generally fill out and submit the claims forms on their own. These currently constitute about 30 percent of part B claims. Diagnostic codes are almost never entered on these forms, and the carriers were not hopeful that this would change. Legislative action requiring practitioners to fill out claims forms in nonassignment cases, such as a provision of a budget act introduced in the 100th Congress (H.R. 3545), would eliminate this problem. It should be noted, in this regard, that diagnostic codes are frequently required for claims submitted by patients to private insurance programs. If this is possible for private insurance, it should be possible for Medicare as well.

Summary of Supplementary Questionnaire

The supplementary questionnaire showed that approximately 30 percent of all part B claims are now entered electronically. These claims generally include one or more ICD-9-CM diagnostic codes. Currently, three quarters of the carriers either use the ICD-9-CM codes when they are found on the paper claims, or could begin to with only minimal start-up costs. One quarter of the carriers would have more significant costs, because of changes they would have to make in their computer software. The carriers identified problems with several types of claims that would have to be overcome before the diagnostic codes could be uniformly collected from all part B claims. Nevertheless, most of the carriers who currently use diagnostic codes in diagnostic-driven screens believe they recapture the added cost of keying in codes through increased claims processing efficiency and better recognition of cases with potentially inappropriate billings.

Examples of Optional Claims Screens Developed by Part B Carriers

The screens for medical claims listed below are examples of the many we collected as part of the carrier survey. These are optional screens, which individual carriers have developed in response to their particular experiences with recurring inappropriate or problematic claims. The first list contains examples of screens based on frequency counts; that is, claims are denied or reviewed for exceeding the covered frequency or dollar limit for a procedure or service, for having inappropriate combinations of procedures, or for claiming noncovered services. All carriers who reported using any optional screens use one or more of this type.

The second list contains examples of diagnosis-driven screens. Billed procedures or services are allowed only in the presence of a qualifying diagnosis. The screens we reviewed are performed manually Reviewers compare the narrative descriptions on the paper claim against a printed list of allowed diagnoses. These screens could be automated if ICD-9-CM diagnostic codes were entered on all part B claims forms.

To compare the two types of screens, the more usual screens based on frequency counts would flag, for example, the fourth electrocardiogram claim in the same month, or the seventh chest X-ray in a quarter. The diagnostic-driven screens would allow an initial electrocardiogram or chest X-ray only when a certain diagnosis or medical problem were present.

Examples of typical optional screens based on frequency counts unrelated to diagnosis are

1. Deny claim if more than three electrocardiograms are billed per month, any provider.

2. Deny claim if more than six chest X-rays are billed per quarter, any provider; exclude inhospital.

3. Suspend claim when three or more components of a complete blood count are performed on the same day by one provider.

4. Suspend claim when all three components of a lipid profile are performed on the same day by one provider.

5. Suspend claim when medical care is billed by different physicians during a hospital stay.

6. Suspend claim when medical visits are billed up to 30 days after surgery by original surgeon.

7. Suspend claim when more than four office visits, all levels of care, are billed per month by one or more provider or place of service.

8. Suspend claim when more than eight services for procedure 9805 (vitamins) are billed per calendar month.

9. Suspend claim for initial consultation when there is a history of prior medical care by the billing physician.

10. Suspend claim when a monthly capitation payment and medical visits are billed within the same calendar month by the same provider.

Examples of optional diagnosis-driven screens are

1. Allow electrocardiograms only for diagnoses on attached list. The number that may be allowed for these covered conditions is noted next to the diagnosis on the list (maintained by carrier).

2. Allow up to 2 chest X-rays in 12 months only for a covered diagnosis on the attached list (maintained by carrier).

3. Suspend claim for procedures 82951 and 82952, unless diagnosis is diabetes, possible diabetes, or hypoglycemia.

4. Allow claim for procedures 85018 through 85580 if diagnosis is anemia, iron therapy, blood loss, hemorrhage, or infection.

5. Allow claim for procedure 82270 for cystic fibrosis, any type of digestive disorder, gastrointestinal bleeding, colon cancer, rectal problems. If other diagnosis, deny.

6. Allow mammograms for diagnoses on attached list (maintained by carrier).

7. Allow computerized tomography scan of pelvis for diagnoses on attached list (maintained by carrier).

8. Allow computerized tomography scan of head for diagnoses on attached list (maintained by carrier).

9. Suspend pay for second office visit (procedures 90015 and 90060) in 1 month for same diagnosis.

10. Allow one office consultation (procedures 90600 through 90620) per month for same diagnosis. Reduce additional claims in the same month to procedure 90640.

Appendix V

Contents of Selected Medicare Statistical Files

The discussion below and accompanying tables describe the data included in the HCFA Medicare files summarized in chapter 5. For each data element listed for each Medicare file, we have indicated, where appropriate, information that could be used to describe individual patient characteristics or the structure, process, or outcomes of care.

Inpatient Hospital and Skilled Nursing Facility Bill Record

Table V.1 contains billing and demographic information on beneficiary hospital stays and skilled nursing facility treatment episodes. Since 1983, this file has also contained information on principal diagnosis and surgical procedures for all hospital stays. Prior to October 1983, diagnosis and procedure information was assembled for a 20-percent sample of Medicare admissions. As bills are cleared by HCFA and the health insurance master file is updated, the enrollee's demographic characteristics are added to the bill information. All bills submitted for the same hospital stay are sorted and summarized to create a bill summary record. When the bill summary indicates that the patient has been discharged, a stay record showing information from date of admission to date of discharge is created. In approximately 95 percent of the cases, the entire stay is on a single bill.

Table V.1: Inpatient Hospital and Skilled Nursing Facility Bill Record

	Provides data on			
Inpatient stay file content	**Patient characteristics**	**Structure of care**	**Process of care**	**Outcome of care**
1 Health insurance claim number				
2 Beneficiary ID code	x			
3 Cross-reference claim number				
4 Beneficiary's name	x			
5 State code of residence	x			
6 County code of residence	x			
7 Date of birth	x			
8 Sex	x			
9 Race	x			
10 ZIP code of residence	x			
11 Medicare status code	x			
12 Current reason for entitlement	x			
13 Original reason for entitlement	x			
14 End-stage renal disease indication	x			
15 HMO indicator		x		
16 Number of HMO periods		x		

(continued)

	Provides data on			
Inpatient stay file content	**Patient characteristics**	**Structure of care**	**Process of care**	**Outcome of care**
17. HMO effective date		x		
18. HMO termination date		x		
19. HMO number		x		
20. HMO option code		x		
21. Bill covers period				
a. From date			x	
b. Through date			x	
22. Query code				
23. Transaction code				
24. Adjustment code				
25. SPIDER indicator[a]				
26. Employment related	x			
27. Provider number		x		
28. Special unit code		x		
29. Intermediary number		x		
30. Date approved				
31. Date forwarded				
32. Date of admission			x	
33. Patient status code				x
34. Discharge date			x	
35. Date of death				x
36. Total covered days			x	
37. Cost report days			x	
38. Lifetime reserve days used	x			
39. Professional component charges			x	
40. Primary payer code				
41. Primary payer amount				
42. Noncovered ancillary charges			x	
43. Inpatient deductible			x	
44. Coinsurance days and amount			x	
a. Days				
b. Rate per day				
c. Total amount				
45. Total deductions				
46. Blood deductible pints			x	
47. Blood deductible charge per pint				
48. Blood deductible charges				
49. Total blood deductions				
50. Blood code				

(continued)

	Provides data on			
Inpatient stay file content	Patient characteristics	Structure of care	Process of care	Outcome of care
51. Blood pints furnished			x	
52. Blood pints replaced				
53. Blood pints not replaced				
54. Blood charge per pint				
55. Total blood charges				
56. Total blood noncovered charges				
57. Noncovered from date				
58. Noncovered through date				
59. Open item from date				
60. Open item through date				
61. Nonpayment code				
62. Total charges				
63. Reimbursement amount				
64. Diagnostic data				
a. Number of diagnostic codes	x		x	
b. Principal diagnosis code			x	
c. Additional diagnosis			x	
65. Surgery data				
a. Number of surgery codes			x	
b. Principal surgery			x	
c. Additional surgery			x	
d. Date of surgery			x	
66. Noncovered charges				
67. End-stage renal disease indicator	x			
68. Qualifying dates				
a. From date			x	
b. To date			x	
69. DRG number			x	
70. Discharge destination				x
71. DRG outlier code			x	
72. Date guarantee of payment began				
73. Date utilization review notice received				
74. Date active care ended				
75. Date benefits exhausted				
76. Outlier amount				
77. HMO paid/readmission indicator				x
78. KRON indicator[b]				
79. Value code				
80. Value code amount				

(continued)

Inpatient stay file content	Provides data on Patient characteristics	Structure of care	Process of care	Outcome of care
81 Revenue center code				
82 Units			x	
83 Service date			x	
84 Rates				
85 Charges			x	
86 Noncovered charges			x	
87 Medical record number				
88 Patient control number				
89 Type of admission			x	
90 Source of admission			x	
91 Admitting diagnosis			x	

[a] The system to provide immediate data on eligibility for reimbursement (SPIDER) is a HCFA data system under development.

[b] Provides information about the bill's Medicare spell-of-illness status.

Medicare Provider Analysis and Review File

The Medicare provider analysis and review file is derived from the inpatient hospital stay record and the provider of services file. Characteristics of the provider are added to selected fields from the hospital stay record. The file is prepared every 3 months and contains 3 years of discharges (the current year and 2 previous years). Table V.2 illustrates this file.

Table V.2: Medicare Provider Analysis and Review File

File content	Provides data on Patient characteristics	Structure of care	Process of care	Outcome of care
1 Health insurance claim number				
2 Age	x			
3 Sex	x			
4 Race	x			
5 Medicare status code	x			
6 State and county of residence code	x			
7 ZIP code of residence	x			
8 Day of admission			x	
9 Discharge status				x
10 KRON indicator[a]				
11 PPS indicator		x		

(continued)

File content	Provides data on Patient characteristics	Structure of care	Process of care	Outcome of care
12. Provider number		x		
13. Provider code		x		
14. Date of admission			x	
15. Date of discharge			x	
16. Length of stay				x
17. Covered days				
18. Coinsurance days	x			
19. Coinsurance amount	x			
20. Inpatient deductible	x			
21. Lifetime reserve days	x			
22. Total charges			x	
23. Covered charges			x	
24. Amount reimbursed				
25. Intensive care days			x	
26. Coronary care days			x	
27. Total accommodation charges			x	
28. Total ancillary charges			x	
29. Intensive care charges			x	
30. Coronary care charges			x	
31. Operating room charges			x	
32. Pharmacy charges			x	
33. Laboratory charges			x	
34. Radiology charges			x	
35. Supplies charges			x	
36. Anesthesia charges			x	
37. Inhalation therapy charges			x	
38. Outpatient service charges			x	
39. Blood administration charges			x	
40. Physical therapy charges			x	
41. Occupational therapy charges			x	
42. Speech pathology charges			x	
43. Other charges			x	
44. Diagnostic data				
a. Number of diagnostic codes				
b. Diagnostic codes			x	
45. Surgery indication			x	
46. Surgical data				
a. Surgical date 1			x	
b. Number of surgical codes				

(continued)

File content	Provides data on Patient characteristics	Structure of care	Process of care	Outcome of care
c. Surgical codes			x	
d. Surgical date 2			x	
e. Surgical date 3			x	
47. Blood furnished (in pints)			x	
48. Original beneficiary indicator code	x			
49. DRG number			x	
50. Discharge destination				x
51. Outlier code			x	
52. Primary payer code				
53. Type of admission	x			
54. Source of admission	x			
55. Professional components				
56. Blood charges			x	
57. Unibill indicator				
58. Primary payer amount				
59. Intermediary number				
60. Payment and edit code				
61. Active care ended date				
62. Outlier amount			x	
63. Kidney acquisition amount			x	
64. Outlier days			x	
65. DRG price				
66. New DRG code			x	
67. New outlier days			x	
68. Health insurance master date of death				x
69. Health insurance master date of death indicator				x
70. Health insurance master social security number indicator				

[a] Provides information about the bill's Medicare spell-of-illness status.

Medicare History Sample File

Table V. 3 presents the Medicare history sample file, which is a longitudinal data base consisting of selected fields from the hospital and medical insurance bill records for a 5-percent sample of beneficiaries.

Table V.3: Medicare History Sample File

	Provides data on			
File content	**Patient characteristics**	**Structure of care**	**Process of care**	**Outcome of care**
Fixed demographic section				
1. Type of record				
2. Hospital insurance claim number				
a. Account number				
b. Equatable beneficiary identification code				
3. Cross-reference claim number				
a. Cross-reference account number				
b. Cross-reference beneficiary identification code				
4. Status of HIC number				
5. Dual entitlement	x			
6. Date of birth	x			
7. Sex code	x			
8. Race	x			
9. Part A dates				
a. Latest entitlement				
b. Latest termination				
c. Prior entitlement				
d. Prior termination				
10. Reason for latest part A termination				
11. Part B Dates				
a. Latest entitlement				
b. Latest termination				
c. Prior entitlement				
d. Prior termination				
12. Reason for latest part B termination				
13. Date of death				x
14. Original reason for entitlement	x			
15. End-stage renal disease indicator	x			
Annual demographic section				
1. Type of record				
2 Reference year				
3. Current reason for entitlement	x			
4. Medicare coverage				
5. Medicare status				
6. Insured status				
7. State and county code of residence	x			

(continued)

File content	Provides data on			
	Patient characteristics	Structure of care	Process of care	Outcome of care
8. ZIP code of residence	x			
9. Group prepaid plan number				
10. State welfare buy-in	x			
Home health agency section				
1. Type of record				
2. Reference year				
3. Part A totals				
a. Visits			x	
b. Charges			x	
c. Other service charges			x	
d. Reimbursement amount			x	
4. Part B totals				
a. Visits			x	
b. Charges			x	
c. Other service charges			x	
d. Reimbursement amount			x	
5. Patient status indicator				x
6. Patient status date				x
Outpatient section				
1. Type of record				
2. Reference year				
3. Outpatient services				
a. Number of bills			x	
b. Covered charges			x	
c. Reimbursement amount			x	
4. Inpatient services				
a. Number of bills			x	
b. Covered charges			x	
c. Reimbursement amount			x	
5. Other services				
a. Number of bills			x	
b. Covered charges			x	
c. Reimbursement amount			x	
Inpatient hospital stay section				
1. Type of record				
2. Reference year				
3. Date of admission			x	

(continued)

	Provides data on			
File content	Patient characteristics	Structure of care	Process of care	Outcome of care
4. Provider data				
a. Number				
b. Type				
5. Date benefits exhausted				
6. Number of covered days				
7. Discharge data				
a. Status				x
b. Date			x	
c. Principal diagnosis code			x	
d. Additional diagnosis indicator			x	
e. Source code				
8. Surgery data				
a. Date			x	
b. Principal surgery code			x	
c. Additional procedure			x	
9. Totals				
a. Charges				
b. Noncovered charges				
c. Deductions				
d. Reimbursement amount				
10. Lifetime reserve days	x			
11. Coinsurance days	x			
Skilled nursing facility stay section				
1. Type of record				
2. Reference year				
3. Date of admission			x	
4. Medicare provider number				
5. Admission data				
a. Diagnosis			x	
b. Additional diagnosis			x	
d. Source of coding				
6. Date benefit exhausted				
7. Number of covered days	x			
8. Discharge data	x			
a. Status				x
b. Date			x	
9. Qualifying stay dates				
a. From date			x	
b. To date			x	

(continued)

	Provides data on			
File content	**Patient characteristics**	**Structure of care**	**Process of care**	**Outcome of care**
10. Totals				
a. Charges			x	
b. Covered charges			x	
c. Coinsurance amount			x	
d. Reimbursement amount			x	
11. Total estimated charge indicator			x	
12. Coinsurance days			x	
Payment record section				
1. Type of record				
2. Reference year				
3. Nonhospital-based services				
a. Number of records			x	
b. Reasonable charges			x	
c. Reimbursement amount			x	
4. Physician services				
a. Number of records			x	
b. Reasonable charges			x	
c. Reimbursement amount			x	
5. Surgical services				
a. Number of records			x	
b. Reasonable charges			x	
c. Reimbursement amount			x	
6. Supplier services				
a. Number of records			x	
b. Reasonable charges			x	
c. Reimbursement amount			x	
7. Hospital services				
a. Number of records			x	
b. Reasonable charges			x	
c. Reimbursement amount			x	
8. Psychiatric charges			x	
9. Unassigned totals				
a. Number of records			x	
b. Reimbursement amount			x	

Part B Medicare Annual Data File

The B-MAD file is a yearly aggregation of data from the carriers' part B claims histories. (See table V.4.) It is composed of four subfiles that provide information on (1) the frequency of each medical procedure, (2) the range of prevailing charges billed for each procedure, (3) a compilation of all procedures rendered by a 5-percent sample of practitioners and suppliers, and (4) the claims history of a 5-percent sample of Medicare supplemental insurance beneficiaries and all end-stage renal disease beneficiaries. The B-MAD beneficiary subfile can be linked, through the hospital insurance claim account numbers, with the various part A files to trace the utilization of services across settings for this 5-percent sample of beneficiaries.

Table V.4: Part B Medicare Annual Data File

	Provides data on			
File content	**Patient characteristics**	**Structure of care**	**Process of care**	**Outcome of care**
Procedure subfile				
1. Pricing locality		x		
2. Specialty		x		
3. HCFA common procedures code			x	
4. HCFA common procedures modifier			x	
5. Place of service		x		
6. Type of service		x		
7. Frequency of the procedure		x		
8. Miles/time/units/services			x	
9. Miles/time/units/services indicator				
10. Submitted charges				
11. Allowed charges				
12. Filler				
13. Frequency of procedure denials		x		
14. Total amount denied				
15. Frequency of procedure edit exclusions		x		
16. Total amount of exclusions				
17. Frequency procedure assigned				
Prevailing charge subfile				
1. Pricing locality		x		
2. Specialty		x		
3. Type of service		x		
4. HCFA common procedures code				
5. HCFA common procedures modifier				
6. Relative value				
7. Conversion factor				
8. 50th percentile value				

(continued)

File content	Provides data on Patient characteristics	Structure of care	Process of care	Outcome of care
9. 75th percentile value				
10. Data origin				
11. Gap fill prevailing charge				
12. Source of gap fill				
13. Adjusted 75th value (participating)				
14. Source of adjustment				
15. Adjusted 75th value (nonparticipating)				
Provider subfile				
1. Provider ID number		x		
2. Pricing locality		x		
3. Specialty		x		
4. Subspecialty		x		
5. Number of physicians and suppliers		x		
6. Address		x		
7. Type of provider		x		
8. Beneficiary claim number		x		
9. HCFA common procedures code and modifier		x		
10. Submitted charge		x		
11. Allowed charge		x		
12. Reimbursement amount		x		
13. Reimbursement indicator		x		
14. Type of service		x		
15. Place of service		x		
16. Date paid		x		
17. Dates of services		x		
18. Miles/time/units/services		x		
19. Miles/time/units/services indicator		x		
20. Assignment indicator		x		
21. Processing indicator		x		
22. Payment indicator		x		
23. End-stage renal disease indicator		x		
24. Carrier control number		x		
Beneficiary subfile				
1. Beneficiary claim number	x			
2. Provider ID number		x		
3. Type of provider		x		
4. Specialty code		x		
5. Sex of beneficiary	x			

(continued)

File content	Provides data on Patient characteristics	 Structure of care	 Process of care	 Outcome of care
6. HCFA common procedures code and modifier			x	
7. Submitted charge			x	
8. Allowed charge			x	
9. Reimbursement amount			x	
10. Reimbursement indicator			x	
11. Type of service		x		
12. Place of service		x		
13. Date paid				
14. Dates of services				
15. Miles/time/units/services			x	
16. Miles/time/units/services indicator				
17. Assignment indicator		x		
18. Processing indicator				
19. Payment indicator				
20. End-stage renal disease indicator	x			
21. Carrier control number		x		
22. Pricing locality		x		

Provider of Services File

The provider of services file illustrated in table V.5 contains information about each institutional provider that participates in the Medicare or Medicaid programs. The data are drawn from state certification forms and periodic updates.

Table V.5: Provider of Services File

File content	Provides data on Patient characteristics	 Structure of care	 Process of care	 Outcome of care
1. Provider number		x		
2. Intermediary number		x		
3. Effective date of participation		x		
4. Date of application		x		
5. Surveyor date		x		
6. State survey agency approval date		x		
7. Termination date		x		
8. Determination approval date		x		
9. Regional office receipt date		x		
10. Category of provider		x		

(continued)

	Provides data on			
File content	Patient characteristics	Structure of care	Process of care	Outcome of care
11. Type of action		x		
12. Eligibility determination		x		
13. Title VI compliance		x		
14. Statement of financial solvency		x		
15. Reason for termination code		x		
16. Information on hospitals not in compliance		x		
17. Status of program compliance		x		
18. Certified beds		x		
19. Total beds		x		
20. Name of hospital		x		
21. Street address		x		
22. City and state		x		
23. ZIP code		x		
24. Type of hospital		x		
25. Type of control		x		
26. State code of hospital		x		
27. County code of hospital		x		
28. State region code of hospital		x		
29. PRO code		x		
30. Authorized date		x		
31. Fiscal year ending date		x		
32. Previous intermediary number 1		x		
33. Previous intermediary number 2		x		
34. Standard metropolitan statistical area code		x		
35. Intermediary type		x		
36. Provider number of parent organization		x		
37. Previous provider number		x		
38. Status code		x		
39. Last transaction code		x		
40. Participation code		x		
41. Facility group		x		
42. Region code		x		
43. Standard metropolitan statistical code area		x		
44. Standard metropolitan statistical area size code		x		
45. Run date of accretion		x		
46. Run date of last transaction		x		
47. Change of ownership count		x		
48. Resurvey count		x		
49. Prior owner's dates		x		

(continued)

File content	Provides data on Patient characteristics	Structure of care	Process of care	Outcome of care
50. Survey date		x		
51. Resident programs approved		x		
52. Facilities and services		x		
a. Blood bank		x		
b. Clinical laboratory		x		
. . . (Lists 33 facilities and services)		x		
53. Number of salaried physicians		x		
54. Number of employees by type		x		
a. Registered nurse		x		
b. Licensed practical nurse		x		
c. Pharmacist		x		
d. Social worker		x		
e. Occupational therapist		x		
f. Speech therapist		x		
g. Physical therapist		x		
h. Other employees		x		
i. Total staff		x		
55. Affiliation with a medical school		x		
56. Accreditation verified		x		
57. Change in accreditation		x		
58. Date approved for emergency services		x		
59. Joint Commission on Accredition of Health Organizations survey date		x		
60. Joint Commission on Accredition of Health Organizations survey status		x		
61. Emergency election code		x		

Medicare Automated Data Retrieval System (MADRS)

MADRS is a new file currently being developed by HCFA to make the retrieval of combined part A and part B data easier and less expensive. It has been designed for use as a data source for research and development projects. It includes information from beneficiaries' part A hospital bills, outpatient bills, skilled nursing facility bills, home health agency bills, and part B physician and supplier records. MADRS includes ICD-9-CM and DRG information from hospital claims, but neither HCFA common procedures codes nor ICD-9-CM diagnostic codes from part B claims. We were unable to obtain a complete listing of data elements in MADRS for inclusion in this report.

Appendix VI

HHS Quality of Care Measurement and Monitoring Studies

The Department of Health and Human Services (HHS) is currently conducting or supporting a number of research projects designed to measure or monitor the quality of care received by Medicare beneficiaries. To address the requester's questions about the focus, direction, and funding of quality-related research activities currently underway or planned by HHS, we sought to identify work being done throughout the agency. Our assessment of the adequacy of this set of activities is developed in chapters 6 and 7. This appendix summarizes the information upon which our assessments were based.

Ongoing HHS studies relevant to this report are listed in table VI.1. They were identified through an iterative process involving a formal request for information submitted to the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and follow-up contacts with agency staff. Determining which studies to include in the tables involved judgments about their scope and objectives. Studies that focus primarily on the structure, process, or outcomes of care provided to Medicare or Medicare-relevant populations and on the development of methods or techniques for measuring quality of care have been included. Several studies focused on the development or testing of methods for case-mix or severity-of-illness adjustments. When the adjustments were intended primarily to examine the relationship of severity of illness to patient outcomes, the studies were included. If they were to refine DRG payment methods, they were excluded.[1]

Although assessing the quality of maternal and pediatric care is clearly very important, studies falling into this category were considered beyond the scope of issues considered here.

We have divided the studies into broad categories reflecting an orientation toward either quality measurement or quality monitoring, acknowledging that this distinction is clearer in theory than in practice. The monitoring studies are more generally focused on issues of detecting changes in quality indicators in some population group over time. Many use existing quality assessment methodologies along with a preintervention-postintervention research design to detect whether changes have taken place in the quality of care received by Medicare beneficiaries

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[1] For example, HCFA has recently funded an evaluation project (not listed in table VI.1) that will examine how different severity adjusters interface with different primary patient classification systems to identify clinically-homogeneous clusters of patients. This project, administered by Queen's University, Canada, will assess the reliability and validity of four patient classification systems unadjusted for illness severity and 11 patient classification systems that represent different combinations of severity adjusters and classification systems. The study is not, however, directly addressing quality assessment issues.

Table VI.1: HHS Studies Measuring Quality of Care

				Variable types			Data types		
	Status	Funding	Change-over-time research design	Structure	Process	Outcome	HCFA files	National	Local
Monitoring studies									
The National DRG Validation Study (Office of the Inspector General and Health Data Institute)	Ongoing	$801,000 (cost plus)			x			x	
Impact of Medicare PPS on Hospital and Post-Acute Care (ASPE/Duke University/Urban Institute)	Ongoing	$150,000	x			x	x	x	
Beneficiary Impact Study (HCFA)	Ongoing	Intramural	x			x	x		
Hospital Mortality Outlier Study (HCFA)	Ongoing	Intramural				x	x	x	
Hospital Practice Study (HCFA and Commission on Professional and Hospital Activities)	Ongoing	$233,000	x		x	x		x	
Health Services Utilization Study (HCFA/Rand)	Ongoing	$616,300			x		x		x
End-Stage Renal Disease Study (HCFA/Urban Institute)	Scheduled completion 1987	$376,000	x	x	x	x	x		
Changes in Post-Hospital Use by Medicare Beneficiaries (HCFA/Abt)	Scheduled completion 1987	$204,000	x		x	x	x		
The Impact of Medicare PPS on Post-Hospital Use Among Medicaid Beneficiaries (HCFA/Abt, subcontracted to SysteMetrics)	Scheduled completion 1987	$112,000	x			x	x		x
A Study of Home Health Care Quality and Cost Under Capitated and Fee-for-Service Payment Systems (HCFA/Center for Health Policy Research, U. Colorado)	Ongoing	$356,000			x	x	x		x

(continued)

				Variable types			Data types		
	Status	**Funding**	**Change-over-time research design**	**Structure**	**Process**	**Outcome**	**HCFA files**	**National**	**Local**
Impact of the PPS on the Quality of Long-Term Care in Nursing Homes and Home Health Agencies (HCFA/Center for Health Policy Research)	Ongoing	$374,000	x		x	x			x
Impact of DRGs on Public Health Nursing Services (NCHSR/University of Virginia)	Ongoing	$229,300	x		x				x
National Medicare Competition Evaluation (HCFA/Mathematica/Medical College of Virginia)	Ongoing	$3,700,000		x	x	x		x	x
Evaluation of the National Rural Swing-Bed Program (HCFA/Center for Health Services Research, U. Colorado)	Scheduled completion 1987	$1,121,800				x	x		
Relative Effectiveness and Cost of Transplantation and Dialysis in End-Stage Renal Disease (HCFA/U. Michigan)	Ongoing	$1,566,000			x	x		x	x
National Hospital Rate-Setting Study (HCFA/Abt)	Ongoing	$90,500				x	x		x
Rehospitalization After Surgery Among Medicare Enrollees (HCFA)	Completed 1986	Intramural				x	x	x	
Relation of Surgical Volumes and Other Factors to Mortality After Surgery (HCFA)	Completed 1986	Intramural				x	x	x	
Outcomes of Nursing Home Discharges (NCHSR&HCTA/UCLA)	Completed 1986	$388,400				x			x
Impact of COSTAR on the Quality of Ambulatory Care (NCHSR&HCTA/U. Nebraska)	Completed 1986	$170,500			x	x			x
Evaluating Outcomes Following Prostatectomy (NCHSR&HCTA/Dartmouth Medical School)	Completed	$76,500				x			x

(continued)

			Change-over-time research design	Variable types			Data types		
	Status	Funding		Structure	Process	Outcome	HCFA files	National	Local
Evaluating Outcomes of Hospital Care Using Claims Data (NCHSR&HCTA/ Dartmouth Medical School)	Ongoing	$1,342,800			x	x			x
Impact of Hospital Discharge Planning on Patient Outcomes (NCHSR&HCTA/Johns Hopkins University)	Scheduled completion 1987	$397,300		x	x	x			x
Measurement studies									
Pilot Study for the Development of Methods for Assessing the Adequacy of Post-Hospital Aftercare Under the Medicare PPS (ASPE/HCFA/ Mathematica)	Ongoing	$1,537,000			x	x	x		x
Nonintrusive Outcomes Study (HCFA/Rand)	Ongoing	$1,000,000			x	x	x	x	x
Clinical Analysis of PPS Impacts on the Quality of Inpatient Medical Care (HCFA/Rand)	Ongoing	$4,500,000	x		x	x	x		x
Health Status at Discharge Project (HCFA/Home Care Northwest Oregon Health Systems)	Completed 1987	$75,000	x			x			x
Development, Pilot Testing, and Refinement of Valid Outcome Measures for the Home Care Setting (HCFA/Home Care Association of Washington)	Ongoing	$189,000				x			x
Mortality-Based Case-Mix Severity Index (HCFA/ Abt, subcontracted to SysteMetrics)	Ongoing	$120,000				x	x	x	
An Automated, Data-Driven, Case-Mix Adjustment System for Studies of Quality of Care (HCFA/U California, San Francisco)	Ongoing	$527,000				x			x

(continued)

				Variable types			Data types		
	Status	Funding	Change-over-time research design	Structure	Process	Outcome	HCFA files	National	Local
Trends in Patterns of Post-Hospital Service Use and their Impacts on Outcomes (HCFA/Duke University)	Ongoing	$300,000	x			x	x	x	x
Develop Indexes of Hospital Efficiency and Quality (HCFA/Commission on Professional and Hospital Activities)	Ongoing	$405,000	x		x	x		x	
Appropriateness of Hospitalization AEP/SMI (HCFA/Michigan Health Care Education Research Foundation)	Completed 1986	$353,300			x				x
Reducing Inappropriate use of Inpatient Services using the AEP (HCFA/University Hospital, Inc., Boston)	Completed 1985	$245,000			x				x
Appropriate and Inappropriate use of Ancillary Services (NCHSR&HCTA/U. Michigan)	Ongoing	$624,600	x		x				x
Patient Characteristics and Head Injury Outcome (NCHSR&HCTA/U. Washington)	Completed 1986	$608,400				x			x
Assessment of Coronary Care Unit Use in Different Hospitals (NCHSR&HCTA/New England Medical Center)	Ongoing	$217,400			x				x
Quality Difference Among Primary Care Practitioners (NCHSR&HCTA/Harvard U.)	Ongoing	To be determined		x	x				x
Developing a Severity of Illness Classification System (NCHSR&HCTA/George Washington University)	Scheduled completion 1987	$1,307,600				x			x

since the introduction of Medicare's prospective payment system (PPS) for inpatient hospital services in 1983. They tend to focus on process and outcome variables that primarily deal with aspects of health service utilization and health status.

The measurement studies are mainly concerned with the development or testing of quality assessment methods. They often explore possible refinements in the measurement of quality of care, address a number of issues regarding the appropriateness of existing data for research in this area, and may incorporate a monitoring component within their framework.

The studies listed in table VI.1 are characterized according to their current status, funding, research designs, the focus of quality of care variables (structure, process, or outcome of care), and the types of data analyzed. In the discussion below, we review some of the particularly important HHS studies currently underway or recently completed, beginning with the monitoring studies, which are categorized according to whether they focus on measurement of health status or outcomes, assessment of the process of care, or some combination of the two. The measurement studies are discussed last.

Direct Assessments of Health Status and Outcomes of Care

Concerns about the appropriateness of hospital discharge decisions under PPS and the availability and quality of posthospital care services are reflected in several HHS-supported studies, which directly assess health status and health care outcomes.

The Aftercare study, developed jointly by ASPE and HCFA and contracted to Mathematica, investigates the types of posthospital care received by Medicare beneficiaries and the adequacy of that care. In the design phase, researchers are developing approaches for measuring the adequacy of posthospital care and its relationship to the care outcomes of individual patients. Specific attention was devoted to the development of instruments for abstracting relevant information from hospital records, refining questions to be administered to posthospital patients (at 2 and 6 weeks after discharge), and refining clinical guidelines for determining the adequacy of aftercare. The instruments and sampling procedures are to be tested in a pilot study conducted at eight hospitals in two states (scheduled to be completed in 1988). A national survey designed to produce estimates of the incidence, nature, and consequences of inadequate care for Medicare patients discharged from hospitals is planned as the third stage of the study.

A recently completed study, the Health Status at Discharge Project funded by HCFA, has developed measures of patient status at discharge, which can be constructed from data contained in patient medical records. In this study, the Northwest Oregon Health Systems developed a summary health status instrument that measures physical and mental status at time of hospital discharge in order to characterize patient dependency levels. The dependency scale was originally constructed with six items: activity, bathing, medications, procedures, symptoms, and age. Scores on these items are computed from information contained in the patient's medical records. In subsequent testing of the instrument, the age and medications items were dropped from the scale. The final version demonstrated high reliability among items in the instrument (alpha-r = .86) and among those administering the instrument (r=.92). This instrument was field tested at four hospitals in the Portland, Oregon, area in 1986 on a sample of 2,622 randomly selected medical abstracts drawn from three medical DRGs and two surgical DRGs. Results obtained with this instrument showed the level of patient dependency to be significantly higher in the post-PPS sample.

The National Center for Health Services Research and Health Care Technology Assessment (NCHSR&HCTA) is also supporting studies focusing on the assessment of patient care in subacute care settings. One study, Outcomes of Nursing Home Discharges, is examining the types of care and care outcomes of patients discharged from nursing homes. The study followed patients for 2 years after they were discharged, tracking their care requirements, including subsequent nursing home and hospital care. Data on patients' care needs and social support characteristics were collected. Researchers will attempt to use the data to define and refine a measure of a "continuing episode of long-term care." Study data also constitute a baseline against which the effects of PPS or other program or policy changes can be assessed. Preliminary analyses showed no changes in pre-PPS and post-PPS assessments of nursing home discharge outcomes, including the proportion dying in skilled nursing facilities, or in returns to the hospital. Comparisons among samples of admissions to nursing homes following hospitalization selected in 1980, 1982-1983, and 1984 showed a marked increase in Medicare admissions in the later samples, as well as modest increases in case-mix (a measure of the overall average diagnostic complexity of the patient populations). However, the changes were observed in the 1980 to 1982-1983 comparisons, as well as in the pre-PPS and post-PPS comparisons.

A second NCHSR&HCTA study is examining the impact of hospital discharge planning on patient outcomes by assessing systematic random samples of patients aged 60 or older after discharge from five acute care hospitals. Information concerning the provider and type of discharge planning is being analyzed to determine how it relates to meeting patient needs in terms of (1) medication and treatment, (2) nursing services and education, (3) rehabilitative care, (4) support services, and (5) continuity of physician care.

Assessing the Process of Care

NCHSR&HCTA has been particularly involved in examining the process of medical care and the appropriateness of medical decisionmaking. One recent study, for example, assessed the effects of using a computerized system for organizing medical records data in ambulatory care settings (COSTAR; see chapter 6) on the quality of care provided in a general medical clinic. A randomized controlled clinical trial was conducted, in which the control group used only the conventional paper record, while the experimental group had access only to the COSTAR record. Six process measures of quality were examined: patient satisfaction, record acquisition speed, record economy, staff acceptance, clinic flows, and compliance with health screening. In addition, the study compared some indicators of patient health, social service interventions, and feedback of information to physicians. The study report has not yet been completed.

An ongoing study, Appropriate and Inappropriate Use of Ancillary Services, is testing criteria for the proper use of five diagnostic tests. The study will attempt to determine whether these criteria sets are effective in modifying physicians' test-ordering behaviors and in encouraging more appropriate and economical use of these services. Another NCHSR&HCTA study, Quality Differences Among Primary Care Practitioners, will use data from over 14,000 episodes of care provided to patients in the Boston area over a 5-year period to examine how staff and practitioner characteristics relate to how care is actually provided. Quality will be measured by comparing the process of care to detailed diagnosis and symptom-specific criteria sets developed in previous research. Specifically, the effect of practitioner gender and role (resident, staff physician, nurse practitioner) will be analyzed. The researchers plan to examine issues such as whether a strong commitment to quality assurance on the part of physicians in leadership roles actually results in higher quality care or whether female practitioners give better care to female patients. They will also attempt to identify staffing patterns likely to provide higher quality care to certain types of patient populations.

Studies Combining Process and Outcomes Data

Another NCHSR&HCTA-funded study, Evaluating Outcomes of Hospital Care Using Claims Data, will combine analysis of computerized billing data with examination of medical records. This study, like the Rand Nonintrusive Outcomes Study discussed below, is designed to evaluate the utility of claims data for identifying possible problems in patient outcomes. Two data sets, Medicare claims data and data collected by the Manitoba Health Commission, will be analyzed. In the first phase of the study, researchers will test hypotheses about the relationship between therapy and outcomes for a subset of conditions and procedures. In the second phase, researchers will validate outcomes for alternative approaches to prostatectomy.

Two studies conducted by the Rand Corporation are attempting to address both process and outcomes in assessing quality of care in the Medicare population. The Clinical Analysis of PPS Impacts on the Quality of Inpatient Medical Care study will produce nationally representative information on two outcome measures (mortality and morbidity) before and after the introduction of PPS. This study involves abstracting extensive information from medical records to determine whether there have been changes in the process of care that have affected the morbidity and mortality of Medicare patients. Expert physician panels are developing treatment standards for six disease categories: hip fracture, myocardial infarction, congestive heart failure, pneumonia, cerebrovascular accident, and depression. These consensus-based explicit standards will identify appropriate appraisal and treatment strategies for each of the six conditions. PPS impacts on quality of care can be assessed by comparing the actual treatment identified in the patient's medical records with the treatment standards established by the physician panels. This strategy is being currently applied to a sample of about 17,000 medical records drawn from hospitals in five states. The results of this study should provide information on the link between treatment performance and quality of care outcomes for the conditions being examined.

Research strategies that link process and outcome variables represent a rigorous approach to reducing measurement error. However, this strategy can rarely be implemented since there are no national-level data systems that incorporate information needed to identify process and outcome indicators of quality. With this issue in mind, Rand has been funded by HCFA to determine the adequacy of existing Medicare data files for providing data on patient outcomes that are sensitive to variations in the quality of health care.

This project, called the Nonintrusive Outcomes Study, is exploring several measurement issues regarding the use of Medicare data for measuring quality of care. The primary objective of this study is to determine whether patient outcomes that can be defined through Medicare part A data adequately and accurately reflect the quality of inpatient care. One aspect of the study focuses on the hospital-specific mortality rates for a set of 48 medical conditions. Data from all Medicare-certified acute care hospitals were analyzed to determine whether individual hospitals have mortality rates (for particular conditions) that vary significantly from expected rates. Further analyses are being performed to determine whether patterns among hospitals identified as having significant differences between their observed and expected mortality rates reflect more than random variation. This second aspect of the study involves comparing the outcomes data derived from Medicare part A records to information abstracted from medical records for two conditions (myocardial infarction and congestive heart failure). Approximately 3,000 medical charts from over 800 hospitals in four states will be reviewed to assess whether outcome indicators based upon claims data can properly classify patients.

Patient Classification Systems and Severity-Of-Illness Adjustment

Patient classification systems are of interest for two reasons. First, they may be used as the basis for determining appropriate levels of reimbursement for different clinical conditions. Second, they may be used to adjust for case-mix differences among hospitals in quality assessment studies.

Medicare's patient classification system based on diagnosis-related groups (DRGs) is used primarily for reimbursement purposes. The system assumes that patients with similar ages, diagnoses, and use of surgical procedures tend to use similar levels of hospital resources. Though this system is widely used, there is recognition that it does not control for within-DRG variation in treatment strategies and patient severity of illness.[2]

Because the DRG system does not adjust within DRGs for severity of illness or for variations in the underlying clinical condition, it is difficult to attribute variations in patient outcomes solely to hospital treatment effects. Only a small number of existing patient classification systems attempt to adjust for variations in the severity levels of patients. In the past, the methodological sophistication of many of these systems has been hampered by data availability and difficulty in specifying the appropriate variables to use in adjusting risk. However, in the last few years research on patient classification systems has made significant strides toward identifying similar risk groups within the Medicare patient population.

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[2] See, for example, S. Jencks, et al., "Evaluating and Improving the Measurement of Hospital Case Mix," Health Care Financing Review Annual Supplement (November 1984), pp. 1-11

HCFA and NCHSR&HCTA have both supported research on patient classification systems. NCHSR&HCTA has been actively involved in the funding of research on case-mix and severity-of-illness measures, including support of the development of the Acute Physiology and Chronic Health Evaluation System. This system is used to evaluate and classify patients treated in intensive care units and is designed to provide predictive information on morbidity and mortality that can be used in assessing both aberrant outcomes and unnecessary use of intensive care services.

A series of HCFA-funded projects, two of which are near completion, should provide further insight into the use of patient classification systems for assessing the quality of medical care. Both SysteMetrics and the Commission on Professional and Hospital Activities (CPHA) have developed patient classification systems that adjust for disease severity as it might relate to hospital mortality. These studies are similar in that they use categorical data analysis techniques to determine risk adjustment factors associated with hospital mortality and use the conceptual logic of the standardized mortality ratio to assess mortality outcomes. However, they use different data bases and have different definitions of hospital-attributable mortality.

The SysteMetrics study involves the construction of models to estimate the effects of age, sex, admission diagnoses, disease severity, and the presence of high-risk comorbidities (additional diseases or conditions) on a 30-day postadmission mortality rate. Disease severity is measured by a technique called "disease staging," which groups clinically-similar diagnostic codes into diagnostic clusters. These clusters are then assigned a severity-of-illness score. The clusters are constructed so that each patient may be assigned mutually exclusive severity scores for principal diagnoses and unrelated comorbidities. Logistic regression models are used to estimate an equation showing the relationship of mortality to the previously described variables. The equations and the coefficients of the variables were estimated from data contained in the 1984 MEDPAR file. (See appendix V.) Average values for these variables in the 1985 Medicare provider analysis and review file were used in the equations to determine risk-adjusted expected mortality counts. Quality of care is then assessed by comparing the expected mortality counts with the observed mortality counts for individual providers.

The Severity Adjusted Mortality Index was developed as part of a larger CPHA project to develop indexes of hospital efficiency and quality. The conceptual framework underlying the construction of this index is similar to the one employed by SysteMetrics in the development of their mortality index. Like the SysteMetrics study, this mortality index uses logistic regression to adjust for patient characteristics, such as principal diagnosis, severity and number of comorbid conditions, age, poverty status, presence of cancer, and race. The index uses the DRG system as a starting point by collapsing into single clusters DRG categories containing similar underlying clinical conditions but differing in terms of age and presence of comorbidities. Within DRG clusters, risk estimates are made by using logistic regression to determine the effects of the variables identified above on the risk of patient mortality. These estimates are derived from data on 6 million patient records contained in the 1983 Professional Activities Survey file maintained by CPHA. Specifically, applying to the survey file data the coefficients of the variables estimated by the logistic regression equation allows CPHA to derive expected mortality counts for each DRG cluster. Quality of care can then be assessed by comparing the observed mortality counts with the expected mortality counts.

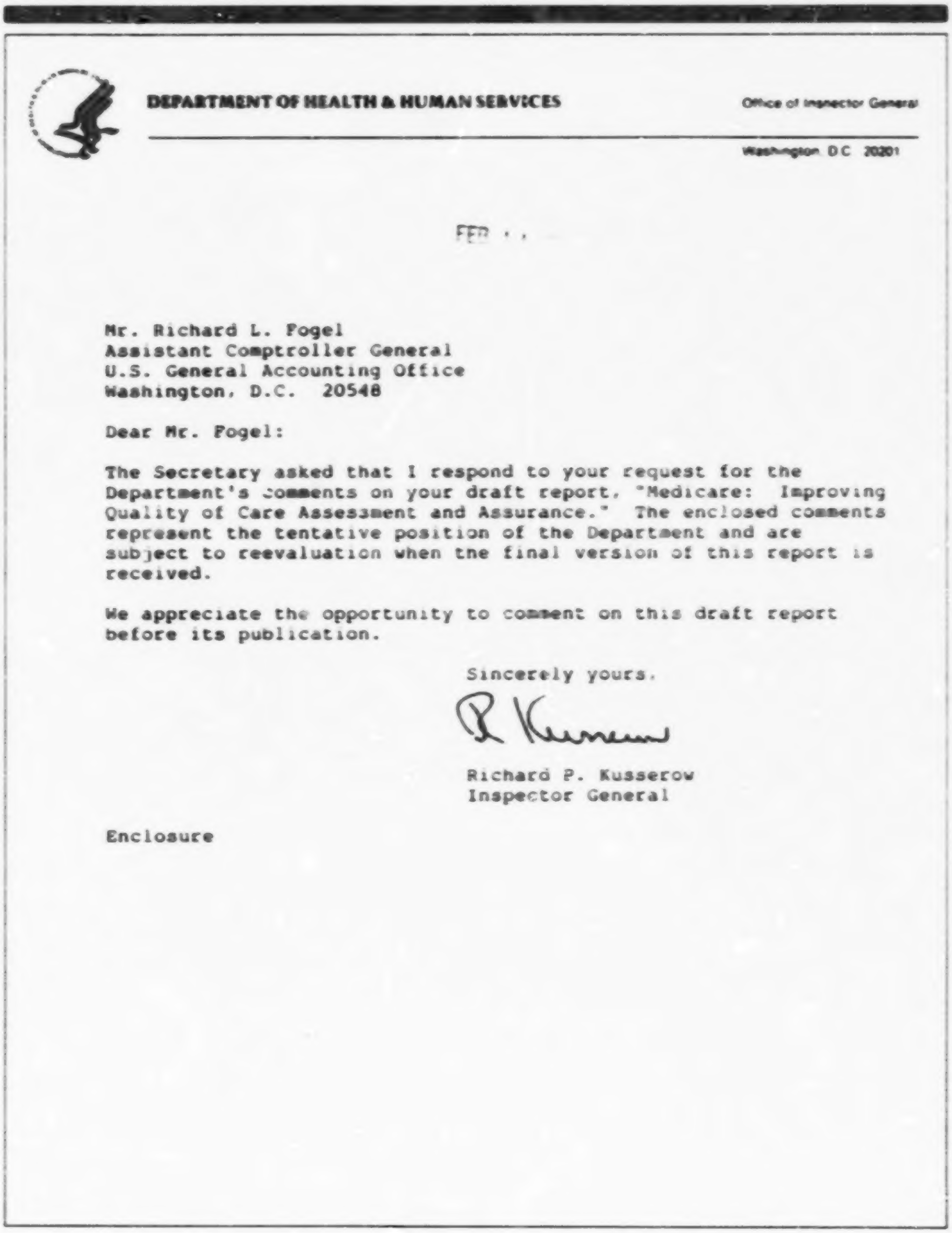
Other HHS work is addressing issues of measurement in posthospital care settings. A study at Duke University will apply a methodology known as grade of membership analysis and life table analysis methods to estimating PPS impacts on the use of skilled nursing facilities and home health services by members of the Medicare population. The integrated use of these two methods represents a methodologically sophisticated attempt to estimate time-dependent, risk-homogeneous probabilities of post-acute care service utilization. Grade of membership techniques will be used to identify subpopulations who are differentiated by their probability of having a set of related medical conditions and physical impairments. By using maximum likelihood estimation techniques inherent in the grade of membership approach, the researchers will be able to identify a number of subgroups that exhibit distinct sets of transition probabilities regarding the use of post-acute health services. These group-related probabilities will then be applied to a Medicare population in the framework of a life table to derive time-specific probabilities of service utilization. Estimates of how individuals with particular characteristics might be likely to use post-acute services will then be calculated from these time-specific transition probabilities.

This project represents an innovative attempt to use multiple data sources; that is, Medicare part A data, Medicaid data, National Long Term Care Surveys, and demonstration project data, to derive probability estimates of post-acute service utilization for an elderly population. It will provide information on PPS impacts on changes in the timing of, selection, and the intensity of service utilization by members of the Medicare population.

Appendix VII

Comments From the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

FEB [illegible]

Mr. Richard L. Fogel
Assistant Comptroller General
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report, "Medicare: Improving Quality of Care Assessment and Assurance." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

Comments of the Department of Health and Human Services on the General Accounting Office Draft Report, "Improving Quality of Care Assessment and Assurance"

Overview

GAO's report was prepared at the request of the Subcommittee on Health, House Committee on Ways and Means and reviews on-going medical review activities, Medicare data resources for measuring and monitoring quality of care, and research and evaluation activities related to quality of care assessment. In general, GAO found that short-term efforts could lead to better information on the effectiveness of the Health Care Financing Administration's (HCFA's) current medical review methods and to significant improvement in the coordination of review activities, the accuracy of the data necessary for effective quality review, and the generalizability of information on the quality of care provided to Medicare beneficiaries. GAO also found that developing a comprehensive quality assurance research base and creating a program for incorporating this knowledge into Medicare quality assurance efforts would require a long-term commitment which cannot be adequately supported by current resources.

More specifically, GAO reports that the effectiveness of the medical review activities of carriers, intermediaries, and Peer Review Organizations (PROs) in identifying quality problems or positively changing physician or provider behavior has not been evaluated. In addition, according to GAO, the data that support medical review as well as the information generated by the reviews are of questionable accuracy. GAO also believes that neither the independent activities of each contract review system, nor the HCFA systems for validating the accuracy of PRO, carrier or intermediary medical reviews generate national estimates of the incidence or distribution of quality problems. Finally, GAO notes that while the Department is supporting many important studies addressing aspects of quality of care measurement, and in particular, studies related to refining the measures of health care outcomes, GAO found that there is no clearly defined strategy or organizational structure for integrating information on the quality of health care provided to Medicare beneficiaries or for developing the underlying methods and knowledge base to meet future needs.

See comment 1

We agree that quality assessment is of such importance that the activities undertaken in that regard should be well considered and coordinated. We disagree with GAO to the extent that it implies that HCFA is not actively engaged in assessing the quality of health care in an orderly manner. In fact, we are involved in a wide range of initiatives focusing on various aspects of quality assessment. Some of these efforts are aimed at assessing quality with existing data and analytic tools, and some of these activities are aimed at developing new and more sophisticated analytic and operational approaches to quality assessment. In addition, at the present time, we are considering several new initiatives which will move the Department forward significantly in quality assessment. The attention afforded the issues involves the most senior levels of HCFA and the Department. As a result, what might appear to be a series of isolated component-specific activities is really quite the opposite.

GAO Recommendation

That the Secretary, HHS, direct the Administrator, HCFA, to assess the comparative effectiveness of carrier and intermediary screens and profiles as a means to identify inappropriate and substandard quality care, as well as to recover Medicare overpayments.

Department Comment

See comment 2

Contractor screens and profiles are effective in the identification of potentially inappropriate care. We agree that an assessment of screens and profiles as a tool to identify poor quality care would be valuable. Such a study would, however, be both costly and time consuming in view of its complexity and the need to collect additional clinical data. In determining whether such a study of contractor screens vis-a-vis quality of care is appropriate at this time, we note that PL 99-509 requires significant expansion of PRO involvement in quality of care assessment beyond the inpatient hospital setting. HCFA is currently developing implementing procedures.

GAO Recommendation

That the Secretary, HHS, direct the Administrator, HCFA, to develop formal guidelines to coordinate the systematic and timely reporting by carriers and intermediaries to PROs of possible problems with the quality of care provided in ambulatory and post-hospital care settings identified in medical reviews. These guidelines should ensure (1) that intermediaries report directly to PROs as well as to HCFA all cases where Medicare coverage for skilled nursing facility or home health services has been denied because patients require a higher level of care, and (2) that information about possible quality of care problems uncovered by carriers is routinely shared with PROs.

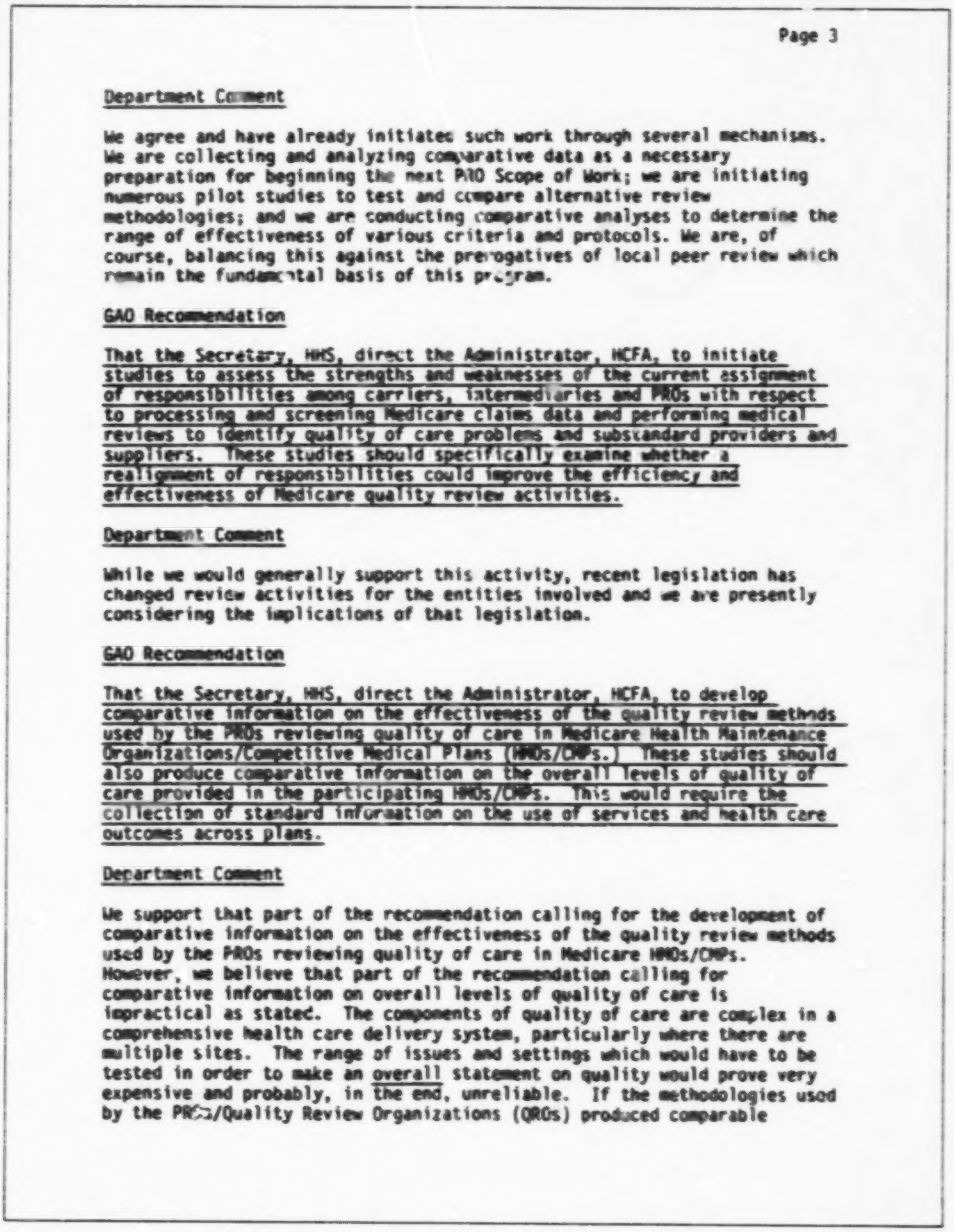
Department Comment

See comment 3

It should be noted that fiscal intermediaries do not "deny" payment because the patient requires a higher level of care. However, we would generally support the referral of quality problems to PROs and will consider the feasibility of doing so over the next several months.

GAO Recommendation

That the Secretary, HHS, direct the Administrator, HCFA, to fund additional studies to analyze the comparative effectiveness of particular PRO review methods, and the utility of current methods for establishing PRO quality objectives. These analyses should include assessments of whether different written review criteria or protocols generate significantly different rates of problems identified, and whether the identification of problems using these methods leads to significant changes in the incidence of quality problems over time.



Department Comment

See comment 4

We agree and have already initiated such work through several mechanisms. We are collecting and analyzing comparative data as a necessary preparation for beginning the next PRO Scope of Work; we are initiating numerous pilot studies to test and compare alternative review methodologies; and we are conducting comparative analyses to determine the range of effectiveness of various criteria and protocols. We are, of course, balancing this against the prerogatives of local peer review which remain the fundamental basis of this program.

GAO Recommendation

That the Secretary, HHS, direct the Administrator, HCFA, to initiate studies to assess the strengths and weaknesses of the current assignment of responsibilities among carriers, intermediaries and PROs with respect to processing and screening Medicare claims data and performing medical reviews to identify quality of care problems and substandard providers and suppliers. These studies should specifically examine whether a realignment of responsibilities could improve the efficiency and effectiveness of Medicare quality review activities.

Department Comment

See comment 5

While we would generally support this activity, recent legislation has changed review activities for the entities involved and we are presently considering the implications of that legislation.

GAO Recommendation

That the Secretary, HHS, direct the Administrator, HCFA, to develop comparative information on the effectiveness of the quality review methods used by the PROs reviewing quality of care in Medicare Health Maintenance Organizations/Competitive Medical Plans (HMOs/CMPs.) These studies should also produce comparative information on the overall levels of quality of care provided in the participating HMOs/CMPs. This would require the collection of standard information on the use of services and health care outcomes across plans.

Department Comment

See comment 6

We support that part of the recommendation calling for the development of comparative information on the effectiveness of the quality review methods used by the PROs reviewing quality of care in Medicare HMOs/CMPs. However, we believe that part of the recommendation calling for comparative information on overall levels of quality of care is impractical as stated. The components of quality of care are complex in a comprehensive health care delivery system, particularly where there are multiple sites. The range of issues and settings which would have to be tested in order to make an overall statement on quality would prove very expensive and probably, in the end, unreliable. If the methodologies used by the PROs/Quality Review Organizations (QROs) produced comparable findings, it would be more appropriate to report on the incidence and distribution of problems found in an HMO/CMP. This data could then be compared across HMOs/CMPs. The information on the incidence and distribution of problems taken together with information on the scope of the internal quality assurance problem would be an indicator of the overall quality of care, but would not provide conclusive information on the quality of care throughout the system. In addition, information on quality problems found in the prepaid setting should be compared to information regarding quality in the fee-for- service setting in order to get a balanced view. However, recommendations on the need for data that can be used to do a comparative evaluation of care in the prepaid setting and the fee-for-service setting were not included in the report.

GAO Recommendation

That the Administrator, HCFA, require that physicians include written descriptions and ICD-9-CM diagnosis codes on Part B claims, that this information be included in the carrier claims processing system, and that it be included in the Part B Medicare Annual Data File (BMAD) and Medicare Automated Data Retrieval System (MADRS).

Department Comment

See comment 7

We are currently considering an expansion of system records to include diagnosis as recommended for assigned claims. Final recommendations will be made subsequent to testing at several sites.

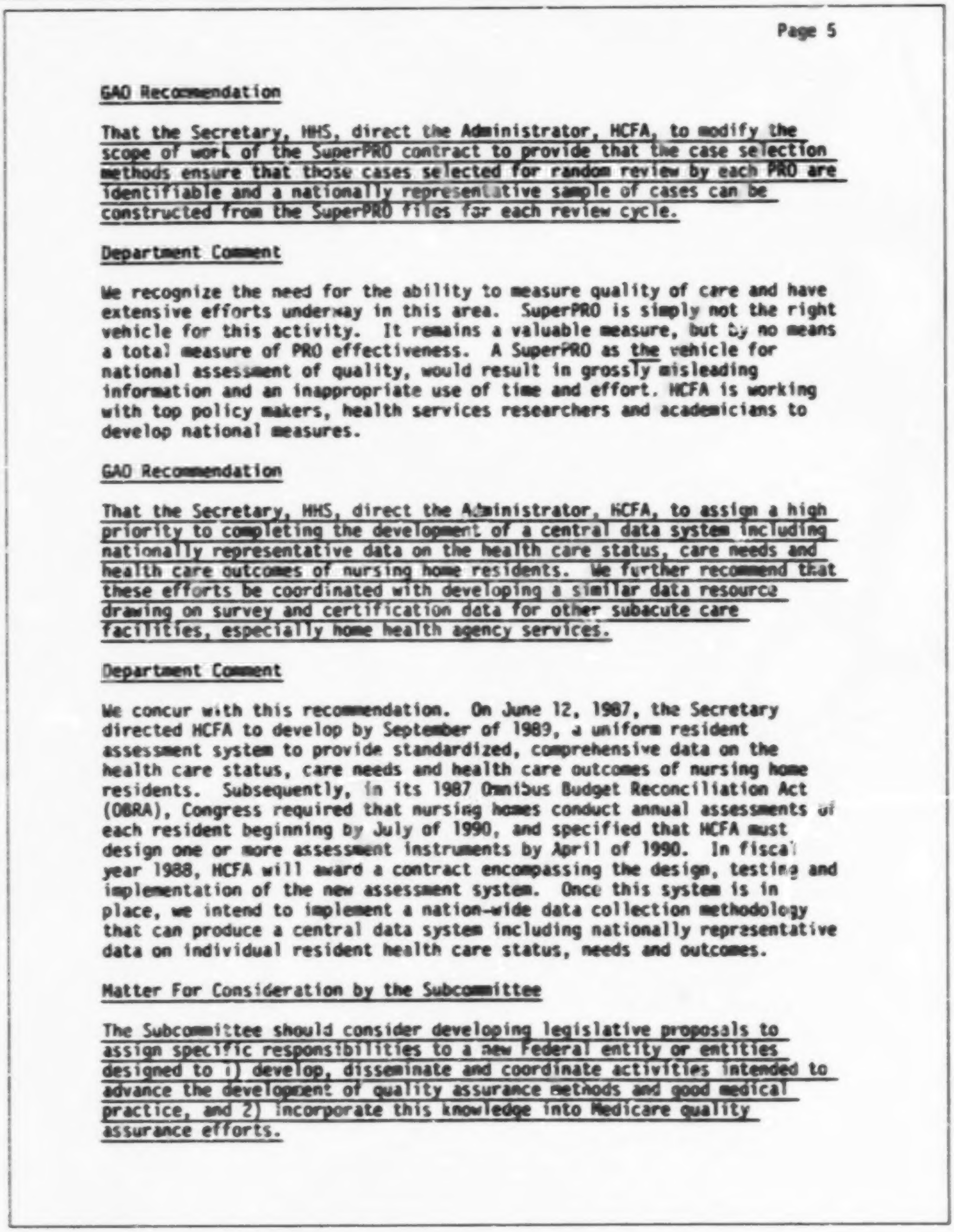
GAO Recommendation

That the Secretary, HHS, direct the Administrator, HCFA, to require PROs, intermediaries and carriers to routinely document and report incidents in which key data elements required for monitoring the quality of care are inaccurate. In particular, errors in mortality (date of death) and discharge destination, as well as all diagnostic and procedure data (not limited to DRG assignment) should be monitored. Tracking errors in the source and type of admission data fields should also be considered.

Department Comment

See comment 8

Current intermediary procedure provides for correcting data errors when they are found. We do not understand the need to report that an error was made. In addition, HCFA routinely appends mortality information developed from SSA's death records to our inpatient (MEDPAR) files. These data could be used to monitor the reporting of deaths which occur in hospitals. HCFA is preparing to use the MADRS files to measure post-hospital care. The monitoring of the discharge destination variable could be done as part of that process.



GAO Recommendation

That the Secretary, HHS, direct the Administrator, HCFA, to modify the scope of work of the SuperPRO contract to provide that the case selection methods ensure that those cases selected for random review by each PRO are identifiable and a nationally representative sample of cases can be constructed from the SuperPRO files for each review cycle.

Department Comment

We recognize the need for the ability to measure quality of care and have extensive efforts underway in this area. SuperPRO is simply not the right vehicle for this activity. It remains a valuable measure, but by no means a total measure of PRO effectiveness. A SuperPRO as the vehicle for national assessment of quality, would result in grossly misleading information and an inappropriate use of time and effort. HCFA is working with top policy makers, health services researchers and academicians to develop national measures.

See comment 9

GAO Recommendation

That the Secretary, HHS, direct the Administrator, HCFA, to assign a high priority to completing the development of a central data system including nationally representative data on the health care status, care needs and health care outcomes of nursing home residents. We further recommend that these efforts be coordinated with developing a similar data resource drawing on survey and certification data for other subacute care facilities, especially home health agency services.

Department Comment

We concur with this recommendation. On June 12, 1987, the Secretary directed HCFA to develop by September of 1989, a uniform resident assessment system to provide standardized, comprehensive data on the health care status, care needs and health care outcomes of nursing home residents. Subsequently, in its 1987 Omnibus Budget Reconciliation Act (OBRA), Congress required that nursing homes conduct annual assessments of each resident beginning by July of 1990, and specified that HCFA must design one or more assessment instruments by April of 1990. In fiscal year 1988, HCFA will award a contract encompassing the design, testing and implementation of the new assessment system. Once this system is in place, we intend to implement a nation-wide data collection methodology that can produce a central data system including nationally representative data on individual resident health care status, needs and outcomes.

See comment 10

Matter For Consideration by the Subcommittee

The Subcommittee should consider developing legislative proposals to assign specific responsibilities to a new Federal entity or entities designed to 1) develop, disseminate and coordinate activities intended to advance the development of quality assurance methods and good medical practice, and 2) incorporate this knowledge into Medicare quality assurance efforts.

Department Comment

See comment 11.

We do not concur with the concept of establishing a new Federal entity. Historically, where there has been cross agency responsibility for an issue or a program, duplication of effort and inadequate communication hinder effective program management. It is possible that there are some internal coordination efforts that might be undertaken and will certainly be considered.

Technical Comments

Now p. 15. See comment 12.

Page 1-11: With regard to better integration of PRO and fiscal intermediary data collection, HCFA's new proposed data collection system will include collection of the beneficiary's health insurance claim number and coded provider identification. Looking beyond the most immediate advantages of this type data collection (e.g. provider and beneficiary specific quality of care data), it also allows for a link to the Part A Medicare inpatient files and other files from which additional data could be retrieved in assessing quality.

Now p. 19. See comment 13.

Page 2-8, Peer Review Organizations, 8th line: Insert "medically" before "necessary".

Now p. 20. See comment 14.

Page 2-10, paragraph 2, revise to read: "PRO contracts negotiated before January 1, 1987 do not reflect those 1986 provisions of OBRA which are effective for contracts entered into or renewed on or after January 1, 1987."

Now p. 20. See comment 15.

Page 2-10, paragraph 2, second sentence, revise to read: "Further, PRO executives...PROs will review SNF, hospital outpatient department, and home health care..." (hospital outpatient department services should be included as they are part of the intervening care review).

Now p. 20. See comment 16.

Page 2-11, line 2, revise to read: "...thirty days of their initial hospital discharge and those initiated by beneficiary complaints. Thus, with the exception of risk- based HMO/CMP services, most PROs are".

Now p. 20. See comment 17.

Page 2-11, line 6: add: "The Pennsylvania PRO is reviewing quality in the post- hospital setting effective 7/1/87 and the Massachusetts PRO will begin this review in March."

Now p. 20. See comment 18.

Page 2-12, first full sentence, revise to read: "Although PROs already had the authority...." Also delete footnote 16. (This is out of date. PROs have been denying inappropriate readmissions/transfers since the implementation of PRO Manual transmittal 85-5 in July 1985.)

Now p. 21. See comment 19.

Page 2-13, footnote 17, revise to read: "Draft rules under review state that payment would be denied for substandard quality care that results in either of the following: (1) It results in an actual, significant adverse effect on the beneficiary, that is, patient management that results in unnecessarily prolonged treatment of the patient, complications in medical conditions, readmission to the hospital, physiological or anatomical impairment, disability, or death; or (2) It presents an imminent danger to the health, safety, or well-being of the beneficiary or unnecessarily places the beneficiary in a high risk situation so as to constitute a gross and flagrant violation on which the PRO may proceed in accordance with 42 CFR 1004.50(a)(2)."

Now p. 26. See comment 20.

Page 3-3: Carriers will process close to 400,000,000 claims in FY 1988. Category 1 screens are front-end denials which may be automated. They are not automatic in that medical policy developed by the carrier is applied by either a claims reviewer or the computer.

Now p. 27. See comment 21.

Page 3-5: The frequency parameters that are established for HCFA mandated screens are thresholds that identify claims for increased scrutiny by medical professionals. These parameters were set based on a distillation of national practice patterns. Carriers' experience in a specific geographic area may suggest that utilization appears higher than warranted. This could lead to a tighter parameter.
The example of a carrier failing to include each HCFA specified code for a mandated screen reflects an individual problem requiring correction. This is not acceptable under existing HCFA policy. However, GAO's report did not identify the carriers or the screens involved.

Now p. 30. See comment 22.

Page 3-12: The FY 1988 Contractor Performance Evaluation Program (CPEP) significantly shifts the emphasis of medical review standards to the accuracy of the medical review determination. Cost effectiveness is still evaluated, but receives significantly less weight in the overall evaluation than in FY 1987.

Now p. 33. See comment 23.

Page 3-16, add after last line: "The fiscal intermediary reports cases to the regional office which in turn refers the cases to the PRO." (This was made clear in a December 14, 1987 memorandum to the regional offices.)

Now p. 35. See comment 24.

Page 3-22, after first full sentence add: "OBRA 1986 requires PROs, effective with contracts entered into or renewed on or after 1/1/87, to review readmissions occurring less than 31 days from the prior admission and to review the intervening care. As this provision is implemented, PROs will be reviewing for quality in outpatient therapies as part of the intervening care review."

Now p. 39. See comment 25.

Page 3-27, Recommendation, 15th line: Third word should be "focusing", deleted additional "1" from problems.

Now p. 42. See comment 26.

Page 4-2, PROs inpatient services section, column 3 add: "Unnecessary transfers/readmissions - circumvention of PPS" and column 4 add: "Number of cases denied payment under Section 1886(f)(2)".

Now p. 42. See comment 27.

Page 4-2: The HMO/CMP review activities also apply to PROs.

Now p. 44. See comment 28.

Page 4-5, third bullet, second line: Should read "...50 percent of transfers to swing beds, 50 percent of...."

Now p. 43. See comment 29.

Page 4-7: Last bullet was deleted because the review activity was removed from the PRO contracts in August 1987.

Now p. 47. See comment 30.

Page 4-14: Last sentence, paragraph 1 should be deleted because nosocomial infection confirmed problems are not treated differently from other confirmed problems. This sentence made it appear as if they were not handled in the same manner.

Now p. 47. See comment 31.

Page 4-15, footnote 11: The first 10 lines appear correct. However, line 11 "Therefore, even though these data come from reviews of the 3 percent random sample...." does not make sense. The 3 percent sample is random so it should not be biased.

Now p. 50. See comment 32.

Page 4-17: "Within 15 days" on line 8 should be deleted because there is no time limit for these denials although PROs focus review on readmits within 15 days.

Now p. 46. See comment 33.

Page 4-19, first paragraph: We have required, since the implementation of the generic quality screens, that the PRO review the total medical record.

Now p. 51. See comment 34.

Page 4-20: Line 8 should be revised because the intensified review level varies depending upon the review category.

Now p. 52. See comment 35.

Page 4-20, PRO Corrective Actions: While the current PRO scope of work does not dictate trigger levels for quality of care issues, the proposed third scope of work will contain prescribed guidelines and interventions for triggering corrective action.

Now p. 54. See comment 36.

Page 4-25. a., third line, revise to read: "...generic quality screens, i.e., discharge planning, nosocomial infections and trauma due to a fall)."

Now p. 58. See comment 37.

Page 4-33: The initial analysis was not performed at each risk based HMO/CMP. It was only performed if the HMO/CMP requested that it be placed on limited review.

Now p. 59. See comment 38.

Page 4-34, first full paragraph, line 5, revise to read: "...proportion of cases are subject to QRO review (see below) as well as a rereview of cases the HMO/CMP reviewed as part of its internal quality assurance program. Plans...."

Now p. 63. See comment 39.

Page 4-41: To better document PRO review efforts but more importantly to facilitate more effective analysis of quality of care and to better focus review efforts, HCFA is proposing to redesign its data collection system. The new system will allow for identification of beneficiary and provider specific review results in order to further our stride towards identification of potential quality problem areas.

See comment 40.

Table 5-1: This table does not include PRO review and reporting of results of premature discharge review performed on every case reviewed, another focus on quality of care which is reported to HCFA monthly.

See comment 41.

Table 5-2: The hospital inpatient stay record file is available in its current form beginning with discharges occurring on or after October 1, 1983. There is also a file of Skilled Nursing Facility data in the same format. The 1981, 1982, and 1983 MEDPAR files contain only one diagnosis and procedure code. The 1984, 1985, 1986, and 1987 files (both fiscal and calendar) are 100 percent files. They do not contain medical school affiliation or bed size. The MADRS data base contains the current and 3 previous years of claims data. MADRS will be used by PROs during this review cycle for studies of post-hospital care.

Now p. 79. See comment 42.

Page 5-33, paragraph 2, lines 6-8: Linking the provision of quality of care across various settings has been proposed in the third PRO scope of work. PROs will utilize HCFA's access to the MADRS file to identify intervening care (skilled nursing facility, home health agency and hospital outpatient departments) for selected readmission cases. PROs will review for the quality of care to determine if care met professionally recognized standards of care and the timeliness of the setting. In fact, the Pennsylvania PRO is currently using MADRS in this regard.

See comment 43.

Table 7-1: We have a number of substantive concerns with the discussion presented in section 7, particularly in table 7.1, concerning HCFA's review process. Table 7.1 states that HCFA has a "weak tradition of sound peer review of research proposals," but does not substantiate this allegation or define what is meant. The report seems to make a qualitative differentiation between the "formally constituted" peer review panel process at NIH/NCHSR and HCTA, and that used by HCFA (wherein new review panels are developed for each grant cycle, with individuals with specific substantive expertise being chosen depending on the anticipated types of proposals to be received for each cycle; these panels are drawn from a standing roster of non-Government and Government experts, with at least 50 percent of each panel being non-Government experts). However, no discussion is offered of what the qualitative differences are--in either direction.

See comment 44.

Table 7.1 also states that "funding decisions (are) driven by policy priorities, sometimes in conflict with technical merit of proposed research." Again, there is no substantiation to support this allegation. In fact, although we have not seen the proposed findings from the recent GAO review of HCFA's Office of Research and Demonstrations referenced in the report, our discussions with GAO on this issue indicated that GAO saw no problems in this area in recent years.

GAO Comments

HHS generally agrees or concurs in principle with all or part of six of our recommendations, does not agree with the need for three recommendations, and does not concur with the matter for consideration by the Subcommittee. As we discuss below, some of the agency comments are predicated on what we believe to be misinterpretations of the recommendations as stated. Others are the result of what seem to be important disagreements about how responsibility for building a quality assurance knowledge base ought to be organized and how that knowledge should be integrated into the operation of the Medicare program.

A number of technical comments are also presented. In some instances, these comments reflect program changes that occurred during the preparation of the draft or while the draft was being reviewed at the agency (such as the enactment of the 1987 Omnibus Budget Reconciliation Act (Public Law 100-203) and the issuance of new Contractor Performance and Evaluation Program criteria); in other cases, suggested changes include the addition of facts, information, or interpretations of regulations or rules which differed from those we obtained earlier from HCFA. In most cases, we have incorporated suggested changes and have indicated substantive changes in the text as appropriate. In several instances, however, we disagree with the points raised by HHS. Specific discussion of these points is presented below.

1. HHS believes that the report implies that "HCFA is not actively engaged in assessing the quality of health care in an orderly manner." We have not stated, nor did we mean to imply, that there is any disorder in discrete HCFA medical review or research activities. What we have emphasized is (1) that these ongoing activities are not well coordinated, and (2) that there is no structure currently in place within HHS to build a knowledge base for quality assessment and assurance that can ultimately provide the information needed by the Medicare program and expected by the Congress. These activities—specifying good clinical practice, incorporating that practice into standards and quality assurance methods, testing incentives for practitioners to adopt such practice standards, and then incorporating these advances into Medicare quality assessment and monitoring their effectiveness—would require a long-term, systematic effort and may need to involve research components of HHS in addition to HCFA's.

We agree that HHS's ongoing work is important, but without a more comprehensive effort to identify potentially what quality care really is, based on sound clinical research, it will be difficult to advance the state of the art. Without more information on the new initiatives HHS is considering, we cannot comment on whether they might bridge what we believe to be gaps in the Department's overall approach to developing quality assessment and assurance methods. The evidence to date, particularly the difficulties that arose with respect to the release of funds for the analysis of patient outcomes authorized by the Omnibus Budget Reconciliation Act of 1986 (see chapter 7), indicates that the coordination of research activities has been problematic.

2. The screening and profiling already performed by intermediaries and carriers to identify potentially inappropriate utilization suggest such tools may also have utility for identifying possible quality of care problems. For example, screens could identify cases of hospital-acquired infections. Quality screens might be most efficiently used by carriers and intermediaries at the point of bill processing to identify potentially substandard quality cases, even if PROS were given major responsibility for making final decisions about quality issues. We believe HCFA should explore the possibilities for improving the overall effectiveness of its medical review systems by testing the feasibility of using screens to target cases of substandard quality. Both the time and cost of developing such a study could be held within acceptable levels if the collection of clinical data were coordinated with PROS' ongoing review activities.

3. We are pleased that HCFA will consider taking actions to ensure that intermediaries and carriers report possible quality of care problems to PROS.

Our wording of the recommendation has been changed to acknowledge that home health care is not denied because a patient requires a higher level of care. There are, however, instances where the interpretation of home health coverage guidelines may lead to denial of payment to patients with extensive care needs. As we understand the regulations, patients requiring more than intermittent care do not, in general, qualify for the Medicare benefit, although there are exceptions. Thus, a patient who could not be placed in an appropriate nursing home setting, or refused to be placed in a nursing home, could be denied Medicare home health care even though he or she had extensive posthospital care needs. The intent of the recommendation is to ensure that if, in the course of reviewing claims, an intermediary or carrier identifies any case where a premature or inappropriate discharge is suspected, even though the patient may not meet Medicare coverage guidelines for the service under review—as well as any other suspected quality of care problem—the PRO be notified. We have changed the wording of the recommendation to make this point clearer.

4. HCFA's initiation of studies to analyze the effectiveness of PRO quality review methods is commendable. However, we do not know the details of the planned evaluation. Thus, we remain concerned about the importance of examining whether review methods can lead to actual changes in the incidence of quality problems over time, as well as their relative effectiveness in identifying cases with possible quality problems.

5. We acknowledge HCFA's need to consider the implications of legislative changes for claims processing and medical review activities. However, the expanded PRO review activities required by Public Law 99-509 should not preclude the screening or profiling of billing data by claims processors to detect possible quality of care problems in order to more effectively organize medical review activities. We believe that studying the possible realignment of review responsibilities among carriers, intermediaries, and PROs would be particularly important in view of HCFA's information system redesign.

6. HCFA supports that part of our recommendation for developing comparative information on the effectiveness of quality review methods used by the PROs in reviewing the quality of care in Medicare HMOs and CMPs. For an initial effort, the evaluation approach suggested by HCFA—that is, reporting information on the "incidence and distribution of problems" found in an HMO or CMP that could be "compared across HMOs and CMPs," along with "information on the scope of the internal quality assurance programs"—would begin to meet the intent of the recommendation.

However, more extensive information must be collected to evaluate quality of care in HMOs and CMPs over the longer term. Without valid and comparable information on the use of services and health care outcomes across plans, it will be extremely difficult to determine whether the process of care within HMOs and CMPs is appropriate. Because PRO review of HMOs and CMPs is just beginning, HCFA has an opportunity to anticipate data needs and plan evaluations that can provide the information needed by the Medicare program, as well as by beneficiaries, on the quality of prepaid care. We believe that with appropriate sampling plans and data collection instruments, HHS could produce valid information for a reasonable cost. In our briefing report, Medicare: Preliminary Strategies for Assessing Quality of Care (GAO/PEMD-87-15BR), we noted that HCFA's objective of developing better information about the quality of care provided to Medicare beneficiaries is in potential conflict with its objective of moving toward systems of prepaid health care that provide less information about patients and their care than is currently available for the fee-for-service population. This recommendation is intended to ensure that potentially serious problems of program accountability do not materialize.

We agree that information on quality of care in prepaid settings should be compared to information regarding quality in fee-for-service settings. The need for a balanced view across both delivery systems is one of the underlying reasons for our discussion in chapter 6 of the need for comprehensive longitudinal information on the use, cost, and quality of care provided to all Medicare beneficiaries. We did not present a recommendation on this issue because we believe that such an ambitious undertaking should be planned as part of the comprehensive research and development activity discussed in chapter 7. However, we are pleased that HCFA agrees that this is an important issue.

7. It is encouraging that HCFA has reconsidered its earlier opposition to requiring diagnostic data on part B physician claims (see GAO/PEMD-87-15BR, p.48) and is willing to test the gathering of such data for assigned claims. Our survey of carriers shows that the collection and use of these data are, at least for some carriers, both feasible and cost-effective. However, we would also urge HCFA to consider testing whether carriers—perhaps drawing upon their corporate experience in handling diagnostic information on commercial health insurance claims—can devise effective systems for obtaining reliable information on unassigned claims.

8. As HCFA notes, intermediaries and carriers currently keep track of data errors that might affect correct billing and return bills for correction when thresholds are exceeded. For example, intermediaries notify hospitals when they enter nonspecific diagnostic codes needed for DRG assignment in more than 10 percent of cases. We believe that similar standards of accuracy should be established for items that might affect quality of care determinations such as discharge destination and type and source of admission, as well as detailed diagnosis and procedure data beyond that needed for reimbursement decisions. One way to begin developing such standards is to keep track of errors uncovered in the course of case review and to allow claims processors the opportunity to work with providers to improve data quality. Over time, this would give physicians and other providers specific incentives to include correct information in billing data fields important for monitoring quality of care. Other issues related to improving data accuracy will be presented in our future report on Medicare patient outcome analyses.

With respect to HCFA's ongoing and planned efforts to improve the quality of data, it should be noted that researchers have found that Social Security Administration death records may also include errors (possibly because the precise date of death within a given month may not affect Social Security benefit calculations). Further, assessing the accuracy of discharge destination data requires confirmation of all posthospital care placements, not just those covered by Medicare. The Medicare automated data retrieval system data will only provide information on Medicare-covered home health or nursing home care, and not placement in private-pay or Medicaid posthospital care.

9. Our recommendation does not suggest that SuperPRO reviews would constitute a "total measure of PRO effectiveness" or that the SuperPRO should be the entity responsible for national assessments of quality of care. Nevertheless, much effort and expense is required to generate SuperPRO data, which are currently not generalizable and therefore relatively useless as an overall effectiveness indicator. The simple addition of a single data element to identify case selection criteria could make SuperPRO data of great interest and utility to policy makers, program administrators, and researchers. We do not understand why SuperPRO reviews, which replicate PRO quality of care and utilization reviews, would result in "grossly misleading" information if performed on appropriate samples.

10. HHS' plan to implement our recommendation regarding the development of a national data system tracking nursing home residents' health care status, needs, and outcomes is an important advance. However, HHS has not indicated plans for creating a similar system for home health care patient data. HCFA is required to collect these data for the facility survey and certification process for home health care providers under the provisions of the 1987 Omnibus Budget Reconciliation Act (Public Law 100-203).

11. The intent of the matter for consideration is to note the need for a clear delineation of responsibility for quality assurance research and development activities. We suggest that this charge be vested in a new federal entity or entities with expanded responsibilities, but we did not preclude existing HHS organizations as potential sites for such activities. Indeed, our discussion of potential sites includes several HHS offices. The matter for consideration has been clarified by the addition of the word "existing" in the phrase "new federal entity or existing entities." The key functions of any such entity—developing basic knowledge about

good medical practice and ways to incorporate this knowledge into quality assessment systems—are not currently the clear responsibility of any HHS agency or office. Thus, we do not agree with HCFA's assertion that this would lead to duplication of effort. Designation of responsibility is essential if the function is to be properly fulfilled. Developing methods for integrating the best standards of medical practice into Medicare quality review is an ancillary activity that could be conducted in or outside of HCFA. HCFA notes the potential for communications problems and we agree; careful coordination and routine exchange of information would be essential.

12. Our discussion of the PRISM system (p. 80) addresses HCFA's planned improvements.

13. The wording has been revised.

14. The wording has been clarified.

15. We have added a footnote indicating that hospital outpatient services will be included in PRO reviews.

16. The phrasing suggested by HCFA has been added.

17. The additional information provided by HCFA is included as a footnote on p. 20.

18. The discussion has been revised.

19. The more complete wording supplied by HCFA has been incorporated into the footnote.

20. The fiscal year 1988 figure supplied by HCFA has been inserted. The term "automatic" was intended to indicate that all cases described by the screen language would be denied payment. The wording has been clarified.

21. We acknowledge, on p. 27, that tighter parameters may be appropriate for some services in some areas. The possibility remains, however, that tighter parameters could mean that services flagged for review in one locality might not be in another. This could, in turn, lead some physicians or suppliers to be more cautious about billing for services and could possibly lead to inconsistent decisions about patient care across

geographic regions. The examples of what appear to be incorrect applications of the mandated HCFA screens are provided here as evidence of variation in screening systems. The focus of this report was on quality of care review activities; full investigation of possible problems with carrier compliance with HCFA policy is beyond the scope of this review.

22. The revised carrier Contract Performance and Evaluation Program criteria were not issued until after HHS received this draft report for comment. Under the revised evaluation system, medical review activities account for 125 of the 1,000 total points a carrier can receive. Cost-effectiveness remains a significant evaluation factor. A maximum score of 30 points is awarded for returning $20.01 or more for each dollar spent on medical review. The accuracy of coverage decisions earns up to 60 points, complying with postpayment review requirements up to 20 points, and applying appropriate HCFA medical review policies up to 15 points. We have added a footnote indicating that revised criteria have been issued. It should also be noted that revised performance and evaluation criteria for intermediaries were published in February 1988.

23. The information provided on the December 14, 1987, memorandum was not available to us at the time the draft was submitted to HHS for reviews. This clarification has been added in a footnote.

24. The reference to PRO review of outpatient therapies has been added as a footnote on p. 35.

25. The typographical errors in the draft have been fixed.

26. PRO review of unnecessary transfers and readmissions has been added to table 4.1, but the details regarding circumvention of PPS and cases denied payment under section 1886(f)(2), which are discussed subsequently in the text, would not be appropriate in a table meant to convey a general overview of PRO activities.

27. The caption identifying HMO and CMP review functions has been changed.

28. The text has been changed to reflect the revised figures, which evidently update those printed in the PRO scope of work.

29. A footnote indicating the change in the scope of work has been added.

30. The sentence referred to by HCFA was intended to emphasize that while nosocomial infections (like falls with injury or untoward effect and failures of the discharge planning screen) need not be referred to the physician reviewer, information on nosocomial infections may be particularly important in identifying problem hospitals. At the agency's suggestion, however, we have deleted the sentence.

31. Both points, that the samples are not comparable across states, and that they cannot be used to make projections about national occurrence rates, are made by HCFA in the material explaining the data cited in this report (see pp. 45-46). The samples cease to be random when they are expanded to include focused review cases and the original random sample is not identified separately. The variations in contract start dates, which resulted in variations in the proportion of cases reviewed by each PRO, also bias the figures.

32. The wording has been clarified.

33. We have amended the text to indicate that the entire medical record must be reviewed, but noted that the information contained in medical records supplied to PROs may vary substantially.

34. The description of intensified review procedures has been revised in accordance with the 1986 PRO scope of work.

35. A footnote describing the proposed threshold for intensified review has been added.

36. The wording supplied by HCFA differs from that in the copy of the PROMPTS-2 document supplied to us. We assume this new wording reflects a revision to the document and have changed the text accordingly.

37. The wording in the text has been clarified.

38. The suggested wording has been incorporated into the text.

39. The redesign of HCFA's data system is discussed in chapter 5, p. 80.

40. Premature discharges have been included in table 5.1; previously, they appeared under the heading "short-stay reviews."

41. The information in table 5.2 has been revised as necessary. More complete descriptions are found in appendix VI.

42. The changes proposed for the PRO new scope of work are consistent with our views on the need for access to linked Medicare data for quality review. They are noted in a footnote in chapter 5 of the report.

43. The discussion of the importance of the peer review process rests on substantive differences between peer review as practiced in the National Institutes of Health (NIH) or the National Center for Health Services Research and Health Care Technology Assessment (NCHSR&HCTA) and the Office of Research and Demonstrations (ORD) of HCFA—differences that, in our view, are important considerations in thinking through how basic developmental work in quality assurance ought to be organized and funded. From its inception, the Center has been grounded in a tradition of and adherence to sound peer review. Much of the impetus for the Center came from the Health Services Research Study Section, which, prior to the creation of the Center, was housed in the Division of Research Grants at the National Institutes of Health and was an integral part of the NIH peer review process. That study section was transferred to the Center and became the nucleus of its peer review activities. Although ORD has made notable efforts to strengthen its peer review activities in recent years, it has not emerged from the NIH/NCHSR&HCTA tradition and peer review is not as firmly established in HCFA.

The Center now has three study sections, each of which is chaired by a full-time executive secretary, who is responsible for managing the peer review process. This involves arranging for 4-year rotating memberships of nonfederal study section members, chosen to reflect the proper mix of substantive, conceptual, and methodological skills to objectively review the technical merit of research proposals assigned to the study section. The executive secretary also arranges for study section meetings as part of the regular grant review cycle; plans site visits to applicants who have submitted promising proposals but from whom additional onsite information is needed in order to reach a review decision; and serves as an ongoing information conduit to the research community about research priorities, the review process, and its results. An important component of the latter is the preparation of "pink sheets," that summarize the deliberations of the review panels, including the recommendation and the priority score assigned by the study section, and are routinely provided to grant applicants. "Pink sheets" provide extremely useful feedback to the applicant, especially in the case of disapproved applications. These attributes of the NCHSR&HCTA review process lend a continuity, commitment, and professionalism that is respected by the research community. This, in turn, enhances the quality of the review process and the research that is ultimately funded.

HCFA, by contrast, does not have a long tradition of peer review. As noted earlier, review panels are created on an ad hoc basis for each review cycle and are drawn from rosters of government and nongovernment experts with appropriate expertise. The panels are chaired by ORD staff who must fit this task in with all their other ongoing responsibilities and have no special training or background for assuming review functions. Summaries of panel deliberations are prepared for HCFA decisionmakers, but no detailed summaries of the substantive review deliberations are routinely provided to applicants.

Because the formally constituted NCHSR&HCTA review panels include only nonfederal experts, we believe they are less likely to subordinate issues of technical merit to concerns about policy relevance or short-term program needs. The language of the House Committee on Energy and Commerce report accompanying H.R. 3189, which extended the NCHSR&HCTA authorization, also clearly expressed the view that the peer review process as exemplified by the NIH model must be primary in making research awards and guaranteeing the quality of research supported by federal funds. We recognize that policy relevance and related program considerations play a greater role in the applied types of research HCFA generally supports. However, the fact remains that the tradition and process of research funding in HCFA provide relatively weaker protections against pressures to subordinate the quality of research to policy considerations. Our review of the HCFA/ORD research process (discussed in the final HHS comment on this report) found that in the period 1983 to 1985, there was considerable evidence that proposals that had been disapproved by HCFA review panels were funded nevertheless. In 1983, eight of the 21 grants funded were disapproved by the panels, and 11 other proposals that were approved by the panels were not funded. While we found that the practice of funding disapproved applications seems to have diminished in recent years, current policies do not ensure that the technical merit of proposals will always be the primary consideration in funding decisions.

44. As stated in the preceding comment, our review of the ORD research process did not indicate that we saw no problems related to the role of policy priorities in making funding decisions. The review found that the situation seems better now than several years ago. The point we are emphasizing, however, is that the peer review and research funding process at HCFA has historically been and continues to be more vulnerable structurally to pressures that could undermine the basic research and developmental activities we discuss in chapter 7 than a system based on an NIH peer review process would be.

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